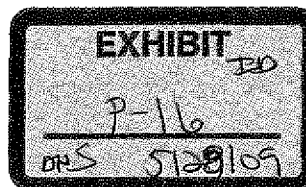


# **EXHIBIT 16**



## Investigation of Deviation Report

P. 1 of 67  
S. S. S. S.  
01/25/08

<b>SECTION I: Preliminary Investigation</b>	Investigation Log No. <u>07-093</u>
Product Name: <u>Digoxin Tablets 0.125 mg (145)</u>	Product Lot No. <u>70924A1</u>
For confirmed OOS, OOS Log No. <u>N/A</u>	
<b>Description of Problem</b> <u>Two tablets of Digoxin tablets 0.125 mg were found with approx. double the thickness from counter channels during packaging /filling operation on packaging line # 405. The incident was noticed by line lead person, Vilas Patel, on 11/30/07 at about 3.15 PM during the packaging of bucket numbers 15 &amp; 16. The Packaging Manager, Dilip Joshi and the Director of Packaging, Ashesh Dave were contacted and informed about this incident. Ashesh Dave instructed him to stop the operation immediately. The QA Supervisor was alerted of the incident and the QA Director was then notified.</u>	
<b>Impact of deviation on the batch (s):</b> <u>The batch (control # 70924A1) has been put on HOLD by QA.</u>	
Prepared by Investigating Department: <u>D. J. M.</u>	Date <u>12-05-07</u>
<b>SECTION II: Investigation, to be prepared by Investigating Director.</b> <b>Briefly Describe Reason for Investigation:</b> The cause of deviation will be investigated by manufacturing dept.	
Assignable Cause(s): Complete table below as per Exhibit A. Or write "EWJ"- Eliminated with Justification. Use this table to document that six categories were addressed to identify the assignable cause.	

Category	Cause-First iteration	Cause-Second iteration	Cause-Third iteration
A. Equipment/facility/ utility	X		
B. Human error	EWJ		
C. Natural causes	EWJ		
D. DOI/batch record	EWJ		
E. API, Ingredient or vendor	EWJ		
F. Product/Process/Packaging	EWJ		
G. Other (specify)	EWJ		

## Section III: CROSS FUNCTIONAL TEAM

Investigation Log No: 07-093

Was a cross functional team assembled to assist in identifying the assignable cause and provide input regarding impact analysis?

☐ No☒ Yes. List member's name and department below

Team Member Name	Department
Dilip Joshi	Packaging
Eric Cardona	Manufacturing
Dan Bitler	QA

## IMPACT ANALYSIS:

Impact on Other Batches and /or products:

The deviation is considered an isolated incident; therefore no other batches are impacted.

Department Head: \_\_\_\_\_

Name/Signature

Date: 01/24/08

## Section IV: CORRECTIVE AND PREVENTIVE ACTION

Describe corrective action(s) and provide an expected completion date

(Attach additional pages if necessary):

As a corrective action, all the tablets that had already been packaged were emptied into bulk containers and a 100% inspection was performed on the entire batch. After the inspection a high level tightened AQL inspection was performed to ensure that the defect tablets have been removed from the batch.

Expected Date of Completion: completedDescribe the action (s) to prevent the recurrence of this deviation. Include both short and long term actions

(Attach additional pages if necessary):

The tablet press operators were trained to remove the tablet deduster and metal detector during start-up the tablets that are produced during machine adjustment can fall directly into the rejection bucket eliminating the possibility of an unacceptable tablet being left on the equipment after adjustments are made.

Expected Date of Completion: completed

Prepared By: \_\_\_\_\_

Name/Signature

Date: 01/25/08

**ACTAVIS TOTOWA LLC.**  
101 EAST MAIN STREET LITTLE FALLS NJ

Date: 1/8/08

To: **Batch File: Digoxin Tablets, USP 0.125mg (145)**  
**Batch Number: 70924A**

From: Michael Ponzo, Quality Assurance

Subject: Investigation 07-093

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01/20/08

On 11/30/07, a packaging operator observed two tablets of the subject batch with approximately double the thickness on the counter channel of packaging line # 405. The lead line operator observed the tablets during the packaging of bucket numbers 15 & 16. The bottles that had already been packaged and the remaining tablets were subsequently placed on hold (H-07-089). Packaging operators were instructed to perform a 100% inspection on the tablets from the hopper (bucket numbers 15 & 16) as well as the two subsequent buckets, numbers 17 & 18. While inspecting bucket number 17, one more tablet was identified, and none were identified in bucket number 18. The remainder of the batch was packaged while operators performed a continuous manual inspection of the tablets as they traveled down the bottle filler channels. While inspecting the final bucket, number 34, two more tablets were identified; bringing the total to five tablets with double the thickness.

Upon notification, the manufacturing department performed a batch record review of the subject batch (See Attachment # 1). Digoxin Tablets, USP 0.125mg are manufactured according to MPR# 14504, revision # 08 and have a batch size of 4.8 million tablets. Manufacturing noted the subject batch was compressed using two tablet presses (press #67, & #71).

Specifications for Digoxin Tablets, USP 0.125mg are as follows:

Weight Range (10 tablets): 1.019g – 1.082g

Thickness Range: 2.0mm – 3.0mm

Hardness Range: 1.0kp – 6.0kp

Every 30 minutes three tablets are sampled from each exit chute of each tablet press and checked for thickness compared to the specifications for the product. Additionally, QA takes 45 samples from each exit chute (1 for each station) at start-up and periodically takes samples while in process to verify weight, thickness, and hardness of each sample. All Start-up and in-process tablet samples from both tablet press machines were found to be within specification (See Attachment # 2)

A review of the finished product testing of the subject batch showed all samples to meet specification for description, identification, friability, assay, content uniformity, dissolution and related substances (See Attachment # 3).

It was noted in the compression data sheet that the press operator had stopped press number 67 and removed the upper and lower punches of the tablet press due to excessive

**ACTAVIS TOTOWA LLC.**

101 EAST MAIN STREET LITTLE FALLS NJ

**Batch File: Digoxin Tablets 0.125mg****Batch Number: 70924A**p. 4 of 67  
Jm  
01/28/08

dust build up on the third day of processing, 11/19/07. When the upper and lower punches were replaced, a new start-up is performed. During start-up the tablet press is re-adjusted to meet the specifications set for the product that is being manufactured. The Manufacturing Manager indicated that the tablets found with double the thickness might have been produced during the re-adjustment at start-up. The possibility that tablets might have gotten stuck in the tablet deduster or metal detector and went unnoticed by the press operator is being considered a possible root cause of the tablets found with double the thickness.

Further review of the compression section of the batch record indicated that tablets from both bucket numbers 17 & 34 were compressed using tablet press number 67. Bucket 17 was filled on 11/19/07 and bucket 34 was filled on 11/20/07 (See Attachment # 4).

A review of the tablet press history was performed. The log indicates that the batch subsequent to the subject batch was also Digoxin Tablets, USP 0.125mg. Manufacturing of this batch started on 11/20/07 and did not indicate tablets manufactured with double the thickness (See Attachment # 5).

An inspection protocol (See Attachment # 6) was issued to have the subject batch 100% inspected in order to remove any tablets that appeared to have double the thickness. The inspection criterion was reviewed with the inspectors prior to the inspection to ensure the acceptability of the product for release to the market. The inspection was completed and a total of 15 tablets with approximately double the thickness were removed from the entire batch. This is in addition to five tablets removed during the packaging operation.

Following the 100% inspection, the QA team conducted a "Tightened" AQL inspection (See Attachment # 7) to ensure that the defect tablets have been removed from the batch. The tightened AQL inspection would require a rejection of the batch if as few as 2 tablets were found to have double tablet thickness. The batch passed the inspection requirements on 1/18/08 (See Attachment # 8 for Inspection Documentation).

#7 was 1/29/08

Based on the inspection results, this batch will be dispositioned to be released.

As a preventative action, tablet press operators were instructed to remove the tablet deduster and metal detector during start-up. With this action the tablets that are produced during machine adjustment can fall directly into the rejection bucket, therefore eliminating the possibility of an unacceptable tablet being left on the equipment after adjustments are made. The deduster and metal detector will be replaced when acceptable limits are achieved.

**ACTAVIS TOTOWA LLC.**  
101 EAST MAIN STREET LITTLE FALLS NJ

**Batch File: Digoxin Tablets 0.125mg      Batch Number: 70924A**

**Root Causes Analysis:**

Although it cannot be confirmed, the root cause of the deviation appears to be an insufficient set up of the Stokes Tablet Press #67 after the new start-up was granted. The Manufacturing Manager indicated that it is possible some tablets might have got stuck in the tablet deduster or metal detector and went unnoticed by the press operator. These double thick tablets could then have fallen into the accepted tablet containers and not the rejected tablet container once the compression machine was granted start-up approval and compression was re-initiated.

**Conclusion:**

The 100% inspection performed on the subject batch eliminated any tablets that were found to have double the thickness. This inspection was ultimately verified by a follow-up AQL inspection supported that there were no double thick tablets remaining in the batch. Both inspections provide support for release of the subject batch.

*Handwritten:* HLT      01/24/08

*Handwritten:* P.5 of 67  
JMS  
01/25/08

## Section IV: QA &amp; REGULATORY EVALUATION

Investigation Log No. 07-093

p 6 of 69  
01/25/08

QA Review Investigation for Completeness and Accuracy and preventive action(s) for appropriateness:

☒ Report Accepted☐ Report Unaccepted

Reviewed By: Quality Assurance

David W. Bittler

Name/ Signature

01/25/08

Date:

The following documents must be filed with regulatory agencies:

A Bittler 01/25/08☒ QA may proceed with product disposition☐ Regulatory Agency Approval required, QA can't proceed with product disposition

Regulatory Affairs/Quality Compliance approval of Deviation Report

David W. Bittler

Name/signature

01/25/08

Date:

## Section V: PRODUCT DISPOSITION

Recommend Disposition of product (s):

Based on the results of this investigation and the  
100% inspection / AQL inspection this batch is acceptable for re-processing and  
subsequent release for distribution as long as all other release criteria have been met.

Approved By: Head, Quality Assurance:

David W. Bittler

Name/ Signature

01/25/08

Date:

If additional pages are attached, Number of pages:

60

Number of attachments:

9

EXHIBIT Ap. 7 of 67  
JMS  
01/25/08

QUESTIONS	CONSIDERATION
Is this a recurring problem	What steps were taken before to resolve Are the conditions the same
A. Is it equipment/laboratory instrument/facility/ utility problem	A.1. Maintenance program inadequate A.2. Malfunction (good maintenance program) A.3. Calibration procedure, ODI or frequency inadequate A.4. Obsolete; requires replacement A.5. Qualification, operation instruction are inadequate A.6. Inadequate equipment/facility design A.7. Environmental (HVAC) A.8. Cross contamination (micro contamination) A.9. Water system failure
B. Is it a human problem	B.1. Inadvertent human error/accident B.2. Job performance problem B.3. Training not given for specific DOI or task B.4. Inadequate training program B.5. Inadequate supervision
C. Is it due to natural causes	C.1. Power failure C.2. Flood C.3. Others-beyond the plant's control
D. Is it a DOI/MOI/batch record problem	D.1. DOI/MOI/batch record format is not operator friendly D.2. DOI/MOI/batch record are not current with practice D.3. Document issuance and control is inadequate D.4. There is no DOI/MOI/form for the task
E. API, ingredient or vendor issue	E.1 Vendor performance problem E.2. MOI need review/revision E.3. Material does not reflect functionality expected E.4. Material was stored improperly E.5. Material was transferred to improper container
F. Product/Process/packaging/test procedure	F.1. Process parameters need to be revised F.2. MOI need revision (specifications are not current) F.3. Formulation needs revision F.4. Container/closure need revision F.5. Labeling/secondary packaging need revision F.6. Test procedure is not reproducible in QC lab



Attachment #1  
Sub  
01/25/08

8/6/07  
Sub  
01/25/08

**Actavis Totowa LLC**

101 EAST MAIN STREET LITTLE FALLS, NJ 07424 USA

**DATE:** 12/15/07

**TO:** Batch File-Digoxin Tablets, USP 0.125mg  
Batch 70924A

**FROM:** Eric Y. Cardona, Manufacturing Manager

**SUBJECT:** Investigation # 07-093

During the packaging of Digoxin Tablets, USP 0.125mg batch #70924A, the line operator found two tablets on the counter channel that seemed to be double the thickness of an average tablet. After management was informed the packaging operation was stopped.

A review of the compression stage was performed.

Digoxin Tablets, USP 0.125mg batch #70924A was compressed using two tablet presses; press #67 in room #119 and press #71 in room #120. Specifications for Digoxin Tablets, USP 0.125mg are as follows: weight range (1.019g – 1.082g), thickness range (2.0mm – 3.0mm), and hardness range (1.0kp – 6.0kp).

The Compression Data Sheet for press #67 was reviewed and it showed that on 11/19/07, the third day of the compression stage, the operator stopped the machine and removed the upper and lower punches for cleaning due to excessive powder build up. The upper and lower punches were cleaned and set back into press #67, and a new start-up was given to QA.

The Compression Data Sheet for press #71 was reviewed and no deviations or comments were recorded.

All in-process tablet tests performed by manufacturing for weight, thickness and hardness for both machines were checked and all were within acceptable limits.

The QA In-Process Compression Start-Up Data Sheet and the Overcheck Data Sheet for press #67 and #71 were reviewed. A total of 765 tablets were checked for thickness and all were within acceptable limits.

**Set-up (Upper and Lower Punches)**

When setting-up the upper and lower punches, the pressure from the lower rollers must be decreased. The pressure is decreased by turning a dial which also controls the thickness of the tablets.

This is done to assure that the upper and lower punches don't come in contact of each other when passing through the section of the pressure rollers without any material in the dies. If the pressure is left on the pressure rollers and there's no material in the dies, the upper and lower punches can be damaged. Even if the punches are rotated around with the hand wheel.

P 9467  
JMB  
01/25/08

An interview with the compression department supervisor was performed to discuss how a thicker tablet can end up in a finished product drum. **(When the room and equipment has been set-up for manufacturing, the tablet deduster and metal detector are placed in line under the tablet discharge chute.)** During the start-up of a product batch, machine adjustments are made to achieve the weight, thickness and hardness specified for the tablets in the MPR. The tablets are then checked. If they are outside acceptable limits the machine is again adjusted to bring tablets within acceptable limits. All tablets during start-up adjustment are vibrated through the tablet deduster and metal detector into a labeled reject bucket. After the start-up adjustment is completed, the reject bucket is placed aside and another bucket is used for acceptable tablets. The press, tablet deduster and metal detector are then inspected to assure that no tablets during adjustment are present. There is a possibility that a tablet or several tablets could have gotten stuck in the tablet deduster or metal detector and went unnoticed by the operator and QA, and actually fell into the acceptable product bucket.

As a preventative action, when adjusting the tablet press at start-up, in order to achieve acceptable tablets, the operator will be instructed that the tablet deduster and metal detector be removed from under the discharge chute of the tablet press. The tablets being produced during the machine adjustments can then fall directly into the reject bucket. This will eliminate the possibility of an unacceptable tablet being left on the equipment after adjustments are made and acceptable limits are achieved.

## Actavis Totowa LLC

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MPR #: 14504	Rev #: 08	Effective Date: 6/16/06	Batch #: 70924A
Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)			
Batch Size: 4,800,000 Tablets			

OPERATING INSTRUCTIONS SECTION V  
PRODUCT RECONCILIATION AND YIELD

COPY

1. Blending Stage:

a. Final Blend Weight	<u>503.25</u> kg
b. Quantity Rejected / Destroyed	<u>0.350</u> kg
c. Quantity of Samples taken (Step # 30, Page # 15)	<u>0.007</u> kg
d. Total Weight (a + b + c)	<u>503.607</u> kg
e. Theoretical Weight	<u>504.0</u> kg
f. Percent Reconciled (d / e) x 100	<u>99.92</u> %
g. Percent Yield (a / e) x 100	<u>99.85</u> %

2. Compression Stage:

h. Usable Tablets Produced	<u>499,240</u> kg
i. Quantity Rejected / Destroyed	<u>1,560</u> kg
j. Quantity of Samples taken (Step # 4, Page # 22)	<u>0.200</u> kg
k. Total Weight (h + i + j)	<u>501,000</u> kg
l. Percent Reconciled (k / a) x 100	<u>99.55</u> %
m. Usable Compressed Tablets (h / 105 mg) x 1,000,000	<u>4,754,666</u> Tablets
n. Theoretical Batch Size	<u>4,800,000</u> Tablets
o. Percent Yield (m / n) x 100	<u>99.06</u> %

NOTE: The Reconciliation should be within 97.0% - 101.0% and the yield should be within 95.0% - 101.0%. If the Reconciliation or yield is outside the range, notify the Department Supervisor and determine the cause of the variance.

REMARKS:

Done By: <u>EV</u>	Date: <u>11/21/07</u>	Checked By: <u>KVP</u>	Date: <u>11/21/07</u>
--------------------	-----------------------	------------------------	-----------------------

Actavis Totowa LLC

## COMPRESSION DATA SHEET

Page 1 of 5

Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg Batch #: 70924A Date: 11/17/07  
11/18/07

Tablet Press Id: 672 Hardness Tester Id: 264 Thickness Gauge Id: 979 Scale Id: 929

Target Weight (1 Tablet): 105.0 mg

Thickness: 2.0 - 3.0 mm

Target Weight (10 Tablets): 1.050 g

Hardness: 1.0 - 6.0 KP

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Every 30 minutes, check ten (10) tablets for aggregate weight and appearance and three (3) tablets for hardness and thickness from each exit chute of the tablet press and compare results to the above product specifications. Record RPM of tablet press upon stabilization of press after every startup, and speed changes

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
	MIC	start	up						SPG										
<sup>pm</sup> 3:45	1.057	OK	2.73	2.73	2.71	3.6	3.4	3.8	SPG	<sup>pm</sup> 3:45	1.048	OK	2.70	2.67	2.68	3.4	3.5	4.0	SPG
	Exit	sy	check						SPG										
	MIC	stop	Fax QA Approval						SPG										
	MIC	start	After QA Approval						SPG										
<sup>pm</sup> 4:30	1.065	OK	2.72	2.70	2.74	4.4	4.1	4.0	SPG	<sup>pm</sup> 4:30	1.055	OK	2.71	2.74	2.69	3.5	3.9	3.7	SPG
4:50	MIC	stop	Fax End of shift						SPG										
	MIC	start	up	11/18/07					AV										
<sup>Am</sup> 7:15	1.047	OK	2.72	2.70	2.74	3.9	4.0	3.3	AV	<sup>Am</sup> 7:15	1.060	OK	2.71	2.72	2.72	3.5	3.5	3.9	AV
Date	<sup>SPG</sup> 11/17/07	AV				Comments:													
Time	<sup>pm</sup> 4:35	<sup>Am</sup> 7:30																	
RPM	22	22																	

\*App = Appearance

&lt;14504-08&gt;

Actavis Totowa LLC

## COMPRESSION DATA SHEET

Page 2 of 5

Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924ADate: 11/18/07

Target Weight (10 Tablets): 1.050 g

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
7:45 <sup>AM</sup>	1.064	OK	2.69	2.73	2.70	4.4	4.3	4.1	AV	7:45 <sup>AM</sup>	1.044	OK	2.75	2.76	2.77	3.8	3.7	3.8	AV
8:15	1.064	OK	2.69	2.67	2.68	3.9	3.8	3.6	AV	8:15	1.056	OK	2.72	2.68	2.80	4.1	3.6	4.0	AV
8:45	1.043	OK	2.67	2.69	2.69	3.7	3.8	3.5	AV	8:45	1.057	OK	2.75	2.70	2.74	3.0	3.1	3.5	AV
9:00	m/c STOP								AV										
11:05	1.055	OK	2.66	2.67	2.65	4.3	3.8	3.9	AV	11:05	1.054	OK	2.69	2.67	2.69	4.3	3.3	4.4	AV
11:35	1.044	OK	2.70	2.68	2.72	3.2	4.3	3.9	AV	11:35	1.051	OK	2.65	2.67	2.66	4.3	4.3	4.4	AV
12:05 <sup>PM</sup>	1.050	OK	2.66	2.69	2.71	5.0	4.6	5.4	AV	12:05 <sup>PM</sup>	1.063	OK	2.69	2.65	2.70	5.4	5.2	5.1	AV
12:35	1.042	OK	2.64	2.66	2.68	4.0	4.5	4.5	AV	12:35	1.051	OK	2.56	2.75	2.65	5.4	4.2	5.4	AV
12:50	m/c stop		Break						AV										
1:15	1.063	OK	2.64	2.69	2.62	4.4	5.1	4.9	AV	1:15	1.051	OK	2.61	2.60	2.62	5.8	5.0	5.6	AV
1:45	1.047	OK	2.68	2.62	2.65	4.5	4.6	5.1	AV	1:45	1.041	OK	2.60	2.63	2.58	4.9	4.4	5.0	AV
2:15	1.066	OK	2.67	2.74	2.72	5.1	4.6	3.2	AV	2:15	1.047	OK	2.64	2.63	2.67	5.0	4.8	3.7	AV
2:45	1.057	OK	2.69	2.70	2.71	5.0	4.1	4.8	AV	2:45	1.051	OK	2.68	2.66	2.63	4.7	4.2	4.0	AV
3:15	1.064	OK	2.66	2.70	2.71	4.4	3.1	4.3	SEA	3:15	1.055	OK	2.71	2.67	2.61	5.1	5.0	4.9	SEA
Date	AV 11/18/07					Comments:													
Time	7:55 <sup>AM</sup>																		
RPM	22																		

\*App = Appearance

&lt;14504-08&gt;

11/18/07  
11/18/07  
11/18/07





Actavis Totowa LLC

## COMPRESSION DATA SHEET

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Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924A

Date: 11/19/07

Target Weight (10 Tablets): 1.050 g

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
11:55 AM	1.059	OK	2.75	2.80	2.63	3.6	3.0	5.2	AV	11:55 AM	1.044	OK	2.55	2.66	2.55	4.9	3.6	4.8	AV
12:25 PM	1.053	OK	2.62	2.68	2.73	4.7	5.7	3.2	AV	12:25 PM	1.053	OK	2.61	2.58	2.59	5.4	5.3	5.7	AV
12:55	1.051	OK	2.55	2.75	2.57	4.4	3.2	5.0	AV	12:55	1.045	OK	2.73	2.57	2.55	4.2	5.1	5.4	AV
1:25	1.040	OK	2.55	2.69	2.73	3.1	4.8	3.0	AV	1:25	1.042	OK	2.65	2.69	2.74	3.8	4.3	3.5	AV
1:28	m/c stop FOR Lunch Break								AV										
2:05	1.060	OK	2.62	2.63	2.64	4.7	5.5	6.0	AV	2:05	1.051	OK	2.73	2.69	2.57	3.7	3.9	5.5	AV
* 2:30	m/c stop								AV										
	m/c start UP								PME										
6:00 PM	1.056	OK	2.66	2.66	2.69	4.7	4.2	4.0	PME	6:00 PM	1.058	OK	2.66	2.67	2.65	4.5	4.4	5.0	PME
	Exit sy check								PME										
	m/c stop for QA Appan L								PME										
	m/c start after QA Appan L								PME										
7:20 PM	1.050	OK	2.63	2.64	2.66	4.2	4.6	4.7	PME	7:20 PM	1.048	OK	2.62	2.64	2.67	4.2	4.2	4.0	PME
7:48	m/c stop End of the day								PME										
Date	11/19/07					Comments: * Stopped, removed & cleaned upper & lower punches due to excessive excessive build-up of powder. OK 11/19/07													
Time	12:20 PM																		
RPM	22																		

\*App = Appearance

&lt;14504-882

Actavis Totowa LLC

## COMPRESSION DATA SHEET

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Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924ADate: 11/20/07

Target Weight (10 Tablets): 1.050 g

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
7:40 AM	1.053	OK	2.66	2.69	2.67	3.9	3.7	4.3	AV	7:40 AM	1.049	OK	2.66	2.69	2.67	3.7	3.8	4.0	AV
8:10	1.064	OK	2.68	2.73	2.66	3.8	3.7	3.5	AV	8:10	1.063	OK	2.69	2.71	2.69	3.3	4.7	3.2	AV
8:40	1.063	OK	2.71	2.75	2.73	3.1	3.3	3.8	AV	8:40	1.040	OK	2.66	2.65	2.61	3.4	4.0	4.1	AV
9:10	1.060	OK	2.77	2.74	2.68	3.0	4.6	4.3	AV	9:10	1.041	OK	2.69	2.62	2.64	3.5	4.5	3.8	AV
9:40	1.052	OK	2.61	2.66	2.65	4.4	5.3	4.4	AV	9:40	1.057	OK	2.66	2.70	2.69	4.8	4.7	4.2	AV
10:10	1.051	OK	2.64	2.70	2.68	3.4	5.3	4.3	AV	10:10	1.047	OK	2.64	2.73	2.65	4.1	3.1	3.8	AV
10:28	m/c STOP FOR Break								AV										
10:55	1.061	OK	2.69	2.63	2.67	4.5	5.2	4.7	AV	10:55	1.061	OK	2.70	2.64	2.69	3.5	4.5	3.8	AV
11:25	1.059	OK	2.69	2.69	2.71	4.0	4.1	4.0	AV	11:25	1.060	OK	2.66	2.69	2.67	4.7	4.1	4.9	AV
11:55	1.045	OK	2.65	2.67	2.69	3.8	5.1	5.0	AV	11:55	1.053	OK	2.67	2.75	2.64	4.0	3.2	5.0	AV
12:25 PM	1.049	OK	2.62	2.61	2.67	4.0	4.4	3.6	AV	12:25	1.044	OK	2.67	2.64	2.61	4.6	3.8	3.0	AV
12:55	1.041	OK	2.57	2.60	2.61	4.5	4.9	4.2	AV	12:55	1.042	OK	2.64	2.65	2.66	4.2	4.6	4.5	AV
1:25	1.048	OK	2.63	2.61	2.64	3.8	4.1	4.0	AV	1:25	1.040	OK	2.60	2.63	2.67	4.0	4.1	4.6	AV
1:30	m/c STOP End of Batch								AV										
Date	11/20/07					Comments:													
Time	8:00 AM																		
RPM	22																		

\*App = Appearance

&lt;14504-08&gt;

11/20/07  
11/20/07  
11/20/07



**Amide Pharmaceutical, Inc.**  
QA In-Process Compression Start Up Data Sheet

**COPY**  
p. 16 of 69  
11/20/07

Product: <b>Digoxin Tablets, 0.125 mg</b>		Batch Number: <b>70924A</b>
Press: <b>67</b>	Number of Stations: <b>45</b>	Side: <b>FRONT</b>
Appearance: <b>A</b>		MPR #: <b>14504-08</b>
Specifications		
Weight (Th. 0.105 g) (0.097 - 0.113) g	Thickness (2.00 - 3.00) mm	Hardness (1.0 - 6.0) kp
Compression Data Sheet signed / Equipment cleared		Verified By: <b>Sam</b> Date: <b>11/17/07</b>

	Weight	Thickness	Hardness
1	0.105	2.70	3.3
2	0.106	2.74	3.7
3	0.108	2.69	3.2
4	0.107	2.71	3.3
5	0.107	2.73	4.6
6	0.106	2.74	4.2
7	0.107	2.73	3.4
8	0.107	2.72	3.9
9	0.106	2.74	3.3
10	0.105	2.71	3.5
11	0.107	2.79	3.3
12	0.106	2.71	4.1
13	0.104	2.74	3.3
14	0.107	2.71	3.9
15	0.106	2.71	3.7
16	0.107	2.72	3.6
17	0.105	2.75	3.6
18	0.107	2.71	3.3
19	0.106	2.71	3.7
20	0.107	2.75	3.8
21	0.106	2.70	3.7
22	0.108	2.71	3.9
23	0.105	2.72	3.4
24	0.107	2.76	3.6
25	0.106	2.73	3.3

	Weight	Thickness	Hardness
26	0.106	2.75	3.6
27	0.104	2.79	3.9
28	0.108	2.76	3.4
29	0.106	2.74	3.4
30	0.104	2.76	3.6
31	0.104	2.73	3.4
32	0.105	2.70	3.3
33	0.106	2.69	3.7
34	0.106	2.68	3.5
35	0.105	2.76	3.1
36	0.106	2.74	3.7
37	0.104	2.76	4.3
38	0.106	2.74	3.7
39	0.104	2.75	3.3
40	0.107	2.70	3.5
41	0.107	2.74	4.6
42	0.105	2.71	3.8
43	0.107	2.73	3.0
44	0.105	2.73	3.5
45	0.107	2.71	3.9
46			
47	N/A		Sam
48			11/20/07
49			
50			

Disposition: Pass  
Analyzed By: Sam  
Reviewed By: Sam

Time: 4:25 pm  
Date: 11/17/07  
Date: 11/20/07

Comments: N/A Sam 11/20/07

Digoxin 0.125 mg Data.F.00

**Amide Pharmaceutical, Inc.**  
QA In-Process Compression Start Up Data Sheet

**COPY**  
p.174 67  
01/16/08

Product: <b>Digoxin Tablets, 0.125 mg</b>		Batch Number: <u>70924A</u>
Press #: <u>67</u>	Number of Stations: <u>45</u>	Side: <b>REAR</b>
Appearance: <u>A</u>		MPR #: <u>14504-08</u>
Specifications		
Weight (Th. 0.105 g) (0.097 - 0.113) g	Thickness (2.00 - 3.00) mm	Hardness (1.0 - 6.0) kp
Compression Data Sheet signed / Equipment cleared		Verified By: <u>Scm</u> Date: <u>11/17/07</u>

	Weight	Thickness	Hardness
1	0.106	2.68	4.3
2	0.107	2.72	3.8
3	0.106	2.74	3.8
4	0.107	2.69	4.3
5	0.106	2.70	4.0
6	0.106	2.72	4.2
7	0.105	2.72	3.8
8	0.105	2.73	3.6
9	0.107	2.73	4.3
10	0.108	2.75	3.8
11	0.105	2.73	4.3
12	0.107	2.73	4.3
13	0.108	2.72	4.3
14	0.106	2.72	4.6
15	0.108	2.76	4.3
16	0.108	2.72	4.0
17	0.106	2.76	4.2
18	0.107	2.73	3.9
19	0.107	2.73	4.3
20	0.107	2.71	4.1
21	0.107	2.71	3.5
22	0.108	2.70	4.3
23	0.107	2.71	3.7
24	0.106	2.78	4.1
25	0.105	2.75	3.5

	Weight	Thickness	Hardness
26	0.106	2.73	4.5
27	0.108	2.70	4.4
28	0.107	2.69	4.1
29	0.106	2.70	3.6
30	0.105	2.73	3.5
31	0.105	2.72	4.1
32	0.104	2.71	3.5
33	0.107	2.69	4.1
34	0.106	2.70	3.7
35	0.105	2.70	3.8
36	0.108	2.72	3.8
37	0.105	2.70	4.0
38	0.106	2.72	4.4
39	0.108	2.68	3.8
40	0.106	2.70	4.6
41	0.107	2.72	3.8
42	0.105	2.75	4.3
43	0.106	2.70	3.9
44	0.107	2.70	4.5
45	0.106	2.72	3.9
46			
47	N/A		Scm
48			11/20/07
49			
50			

Disposition: Pass  
 Analyzed By: Scm  
 Reviewed By: Scm

Time: 4:25 pm  
 Date: 11/17/07  
 Date: 11/20/07

Comments: N/A Scm 11/28/07

Digoxin 0.125 mg Data.R.00

**Amide Pharmaceutical, Inc.**  
QA In-Process Compression Start Up Data Sheet

COPY

Product: <b>Digoxin Tablets, 0.125 mg</b>		Batch Number: <b>70924</b>
Press #: <b>67</b>	Number of Stations: <b>45</b>	Side: <b>FRONT</b>
Appearance: <b>A</b>		MPR #: <b>14504-08</b>
Specifications		
Weight (Th. 0.105 g) (0.097 - 0.113) g	Thickness (2.00 - 3.00) mm	Hardness (1.0 - 6.0) kp
Compression Data Sheet signed / Equipment cleared    Verified By: <b>MMR</b> Date: <b>11/19/07</b>		

	Weight	Thickness	Hardness
1	0.104	2.65	4.1
2	0.105	2.65	3.5
3	0.106	2.68	4.2
4	0.103	2.66	3.9
5	0.104	2.64	4.0
6	0.107	2.65	3.8
7	0.105	2.69	3.5
8	0.104	2.67	4.2
9	0.106	2.64	3.5
10	0.105	2.62	3.7
11	0.107	2.65	4.1
12	0.104	2.66	3.8
13	0.108	2.63	3.4
14	0.105	2.61	3.7
15	0.106	2.65	3.6
16	0.105	2.64	3.8
17	0.104	2.62	4.0
18	0.106	2.66	3.4
19	0.103	2.62	4.1
20	0.105	2.66	4.2
21	0.104	2.61	4.6
22	0.107	2.63	4.2
23	0.106	2.64	3.6
24	0.105	2.66	4.3
25	0.107	2.65	4.1

	Weight	Thickness	Hardness
26	0.104	2.63	3.3
27	0.105	2.66	3.9
28	0.103	2.68	4.2
29	0.104	2.64	3.5
30	0.106	2.63	3.7
31	0.105	2.65	3.7
32	0.107	2.67	4.1
33	0.103	2.64	4.2
34	0.105	2.65	4.0
35	0.106	2.70	4.5
36	0.104	2.65	4.6
37	0.105	2.64	3.9
38	0.103	2.68	3.8
39	0.106	2.67	3.6
40	0.105	2.62	4.1
41	0.103	2.65	3.9
42	0.106	2.63	3.5
43	0.105	2.60	3.8
44	0.104	2.59	4.3
45	0.105	2.64	3.7
46			
47			Scm
48	N/A		11/20/07
49			
50			

Disposition: Pass  
 Analyzed By: MMR  
 Reviewed By: Scm

Time: 6:55 PM  
 Date: 11/19/07  
 Date: 11/20/07

Comments: m/c stopped b/w removing & cleaning  
of upper & lower punches due to the  
excessive build up of powder      Scm 11/19/07  
Scm 11/19/07

Digoxin 0.125 mg-Data.F.00

**Amide Pharmaceutical, Inc.**  
QA In-Process Compression Start Up Data Sheet

**COPY**  
11/19/07

Product: <b>Digoxin Tablets, 0.125 mg</b>		Batch Number: <b>70924A</b> of <b>105/08</b>
Press #: <b>67</b>	Number of Stations: <b>45</b>	Side: <b>REAR</b>
Appearance: <b>A</b>		MPR #: <b>14504-08</b>
Specifications		
Weight (Th. 0.105 g) (0.097 - 0.113) g	Thickness (2.00 - 3.00) mm	Hardness (1.0 - 6.0) kp
Compression Data Sheet signed / Equipment cleared    Verified By: <u>mmp</u> Date: <u>11/19/07</u>		

	Weight	Thickness	Hardness
1	0.105	2.72	4.1
2	0.102	2.64	3.7
3	0.103	2.66	4.1
4	0.104	2.70	4.2
5	0.106	2.69	4.4
6	0.105	2.71	4.0
7	0.106	2.70	3.8
8	0.105	2.68	3.6
9	0.102	2.71	3.8
10	0.107	2.69	3.5
11	0.105	2.71	4.4
12	0.107	2.71	3.8
13	0.104	2.71	4.0
14	0.103	2.69	4.3
15	0.105	2.68	3.7
16	0.104	2.71	4.3
17	0.106	2.73	3.9
18	0.105	2.70	3.3
19	0.104	2.69	4.1
20	0.108	2.69	3.8
21	0.106	2.71	4.1
22	0.105	2.68	3.8
23	0.104	2.66	3.7
24	0.106	2.69	4.2
25	0.105	2.68	3.9

	Weight	Thickness	Hardness
26	0.103	2.70	3.4
27	0.105	2.72	3.9
28	0.107	2.70	4.4
29	0.104	2.67	4.0
30	0.104	2.72	3.5
31	0.105	2.67	3.9
32	0.103	2.66	4.1
33	0.106	2.65	3.2
34	0.105	2.67	3.8
35	0.107	2.70	3.7
36	0.104	2.68	3.3
37	0.105	2.66	3.6
38	0.103	2.71	3.9
39	0.105	2.65	4.0
40	0.106	2.67	3.6
41	0.103	2.73	3.7
42	0.105	2.67	3.7
43	0.104	2.65	4.1
44	0.107	2.68	4.0
45	0.105	2.65	4.2
46			
47			Scm
48	N/A		11/20/07
49			
50			

Disposition: Pass  
Analyzed By: mmp  
Reviewed By: Scm

Time: 6:55 AM PM  
Date: 11/19/07  
Date: 11/20/07

Comments: N/A - Scm 11/19/07

Digoxin 0.125 mg Data R.00

AMIDE PHARMACEUTICAL, INC  
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

WEIGHT

BATCH 70924APRODUCT Digoxin Tablets 0.125 mg

COPY

PRESS.NO 67SIDE FrontTHEO. 0.105gmRANGE 0.097 --- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:20 AM	0.103	0.109	0.106	0.108	0.105	0.106	0.105	0.107	0.106	0.105	P	Scm ASR
11/18/07	8:20 AM	0.105	0.102	0.103	0.103	0.103	0.102	0.102	0.102	0.105	0.102	P	Scm ASR
11/18/07	11:30 AM	0.104	0.103	0.104	0.105	0.103	0.103	0.106	0.105	0.102	0.105	P	Scm ASR
11/18/07	12:30 PM	0.102	0.103	0.104	0.106	0.103	0.103	0.105	0.106	0.104	0.105	P	Scm ASR
11/18/07	1:30 PM	0.108	0.102	0.104	0.106	0.105	0.106	0.103	0.104	0.106	0.110	P	Scm ASR
11/18/07	2:30 PM	0.106	0.109	0.105	0.107	0.105	0.106	0.107	0.107	0.103	0.105	P	Scm ASR
11/18/07	3:30 PM	0.105	0.106	0.105	0.105	0.105	0.103	0.103	0.108	0.106	0.105	P	ASR
11/18/07	4:00 PM	0.106	0.105	0.106	0.107	0.106	0.105	0.105	0.106	0.105	0.106	P	Scm
11/18/07 11/19/07	7:50 AM	0.104	0.105	0.110	0.106	0.105	0.105	0.105	0.104	0.106	0.106	P	Scm ASR
11/19/07	8:50 AM	0.103	0.110	0.102	0.103	0.102	0.103	0.107	0.102	0.106	0.104	P	Scm ASR
11/19/07	9:50 AM	0.106	0.104	0.107	0.106	0.109	0.106	0.108	0.106	0.108	0.106	P	Scm ASR
11/19/07	11:00 AM	0.104	0.101	0.102	0.107	0.103	0.105	0.102	0.103	0.104	0.102	P	Scm

REV ScmDATE 11/20/07

11/20/07  
11/20/07  
11/20/07



Amide Pharmaceutical, Inc.  
QA IN - PROCESS COMPRESSION OVER CHECK DATA SHEET

THICKNESS / HARDNESS

PRODUCT Digoxin Tablets 0.125mg

BATCH 70924A

COPY

PRESS NO 67SIDE FRONT

DATE	TIME	THICKNESS					HARDNESS					DISP	BY
		RANGE (2.0 ---- 3.0 )mm					RANGE (1.0 ----- 6.0 ) kp						
		1	2	3	4	5	6	7	8	9	10		
11/18/07	7:20Am	2.69	2.72	2.76	2.75	2.75	3.8	3.9	3.6	3.1	4.3	P	Scm ASR
11/18/07	8:20Am	2.68	2.66	2.71	2.69	2.65	3.6	3.6	3.2	3.2	3.4	P	Scm ASR
11/18/07	11:34Am	2.68	2.68	2.69	2.70	2.75	3.4	3.2	3.1	3.6	3.0	P	Scm ASR
11/18/07	12:30Pm	2.66	2.62	2.67	2.61	2.80	3.0	4.2	4.5	2.8	3.2	P	Scm ASR
11/18/07	1:30Pm	2.67	2.64	2.66	2.63	2.63	4.4	4.0	3.6	4.6	5.0	P	Scm ASR
11/18/07	2:30Pm	2.63	2.61	2.84	2.67	2.63	5.1	5.3	4.4	4.8	5.1	P	Scm ASR
11/18/07	3:30Pm	2.64	2.69	2.64	2.64	2.70	4.5	4.8	5.0	4.7	4.7	P	Scm ASR
11/18/07	4:00Pm	2.64	2.72	2.68	2.65	2.70	5.7	5.4	5.0	4.9	5.8	P	Scm ASR
11/19/07	7:50Am	2.61	2.68	2.64	2.70	2.71	3.8	3.8	4.6	3.9	4.6	P	Scm ASR
11/19/07	8:50Am	2.55	2.64	2.59	2.67	2.64	4.2	3.2	4.3	3.0	2.6	P	Scm ASR
11/19/07	9:50Am	2.65	2.66	2.67	2.89	2.64	3.4	3.3	3.9	4.0	4.5	P	Scm ASR
11/19/07	11:00Am	2.79	2.69	2.71	2.83	2.70	4.5	3.3	3.4	3.0	3.1	P	Scm ASR

REV. BY ScmDATE 11/20/07

PLAINTIFFS' EXHIBITS 000022

COPY

11/21/07  
JMS  
01/15/08

AMIDE PHARMACEUTICAL, INC  
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

WEIGHT

BATCH 70924A

COPY

PRODUCT Digoxin Tablets 0.125 mgPRESS.NO 67SIDE RearTHEO. 0.105gmRANGE 0.097 ---- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:20 AM	0.106	0.108	0.106	0.107	0.106	0.107	0.108	0.105	0.106	0.106	P	Sam ASR
11/18/07	8:20 AM	0.104	0.101	0.107	0.104	0.106	0.106	0.106	0.105	0.104	0.106	P	Sam ASR
11/18/07	11:30 AM	0.102	0.103	0.106	0.105	0.104	0.108	0.105	0.104	0.106	0.104	P	Sam ASR
11/18/07	10:30 PM	0.104	0.104	0.104	0.106	0.104	0.105	0.105	0.105	0.104	0.108	P	Sam ASR
11/18/07	12:30 PM	0.105	0.105	0.104	0.104	0.107	0.105	0.106	0.106	0.105	0.104	P	Sam ASR
11/18/07	1:30 PM	0.104	0.103	0.106	0.104	0.103	0.107	0.105	0.104	0.104	0.105	P	Sam ASR
11/18/07	3:30 PM	0.104	0.102	0.105	0.103	0.104	0.103	0.104	0.103	0.106	0.105	P	Sam ASR
11/18/07	4:00 PM	0.103	0.104	0.102	0.103	0.104	0.105	0.104	0.104	0.107	0.104	P	Sam ASR
11/19/07	7:50 AM	0.107	0.106	0.108	0.108	0.105	0.106	0.103	0.106	0.105	0.107	P	Sam ASR
11/19/07	8:50 AM	0.103	0.105	0.104	0.103	0.102	0.104	0.105	0.105	0.105	0.104	P	Sam ASR
11/19/07	9:50 AM	0.107	0.105	0.105	0.105	0.104	0.105	0.107	0.105	0.104	0.105	P	Sam ASR
11/19/07	11:00 AM	0.104	0.105	0.109	0.106	0.105	0.105	0.104	0.105	0.105	0.107	P	Sam ASR

REV SamDATE 11/20/07

11/22/07  
11/20/07

## QA IN-PROCESS COMPRESSION OVER CHECK DATA SHEET

THICKNESS/ HARDNESS

PRODUCT Digoxin Tablets 0.125 mg

COPY

Batch 70924APRESS NO 67SIDE Rear

		THICKNESS					HARDNESS						
		RANGE (2.0 ---- 3.0)mm					RANGE (1.0---6.0)kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:20 AM	2.76	2.73	2.77	2.76	2.77	3.8	3.6	3.4	3.8	3.9	P	Sam ASR
11/18/07	8:20 AM	2.68	2.69	2.70	2.73	2.69	4.0	4.1	4.0	4.0	3.9	P	Sam ASR
11/18/07	11:30 AM	2.68	2.66	2.81	2.71	2.69	3.8	4.3	2.9	4.1	4.2	P	Sam ASR
11/18/07	12:30 PM	2.60	2.62	2.75	2.61	2.60	5.4	5.4	4.9	2.9	5.4	P	Sam ASR
11/18/07	1:30 PM	2.60	2.63	2.67	2.76	2.62	3.1	5.4	5.1	5.0	4.8	P	Sam ASR
11/18/07	2:20 PM	2.65	2.66	2.64	2.67	2.72	3.2	4.7	4.9	4.9	4.6	P	Sam ASR
11/18/07	3:30 PM	2.59	2.64	2.61	2.63	2.60	4.9	4.1	4.3	4.7	4.4	P	Sam ASR
11/18/07	4:00 PM	2.58	2.59	2.59	2.61	2.61	4.6	5.5	5.2	4.8	5.5	P	Sam ASR
11/19/07	7:50 AM	2.65	2.86	2.64	2.64	2.66	4.5	2.9	4.1	4.6	4.9	P	Sam ASR
11/19/07	8:50 AM	2.67	2.63	2.58	2.60	2.71	4.1	4.3	2.5	4.4	4.3	P	Sam ASR
11/19/07	9:50 AM	2.62	2.64	2.63	2.77	2.64	3.6	4.8	3.6	4.3	5.0	P	Sam ASR
11/19/07	11:00 AM	2.70	2.68	2.62	2.80	2.82	3.1	2.9	3.0	4.9	3.3	P	Sam ASR

REV. BY SamDATE 11/20/07

COPY

p 23 of 67  
01/21/08



AMIDE PHARMACEUTICAL, INC  
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

WEIGHT

BATCH 709244PRODUCT Digoxin Tablets 0.125 mg

COPY

PRESS.NO 67SIDE FrontTHEO. 0.105gmRANGE 0.097 ---- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	12:00 pm	0.107	0.103	0.105	0.104	0.109	0.105	0.105	0.102	0.108	0.106	P	Sam ASR
11/19/07	1:00 pm	0.103	0.105	0.108	0.103	0.108	0.105	0.103	0.104	0.103	0.104	P	Qum
11/19/07	2:10 pm	0.107	0.106	0.109	0.103	0.109	0.108	0.106	0.104	0.105	0.110	P	Sam
11/20/07	7:45 AM	0.106	0.102	0.111	0.106	0.105	0.107	0.104	0.109	0.105	0.109	P	Qum
11/20/07	8:45 am	0.106	0.104	0.103	0.108	0.105	0.106	0.105	0.106	0.106	0.104	P	mmf ASR
11/20/07	9:50 am	0.105	0.106	0.104	0.107	0.103	0.105	0.104	0.105	0.108	0.106	P	mmf ASR
11/20/07	11:00 AM	0.106	0.105	0.105	0.104	0.103	0.103	0.106	0.106	0.105	0.107	P	Sam ASR
11/20/07	12:00 pm	0.103	0.104	0.104	0.104	0.105	0.105	0.104	0.104	0.105	0.104	P	Sam ASR
11/20/07	1:00 pm	0.105	0.105	0.104	0.104	0.105	0.103	0.104	0.106	0.104	0.105 0.105	P	Qum
					N/A			Sam		11/20/07			

REV SamDATE 11/20/07

\* M/C stopped, removed & cleaned upper  
& Low punches due to the excessive  
build up of powder - Sam 11/19/07

Amide Pharmaceutical, Inc.  
QA IN - PROCESS COMPRESSION OVER CHECK DATA SHEET

THICKNESS / HARDNESS

PRODUCT Digoxin Tablets 0.125mgCOPY BATCH 70924APRESS NO 67SIDE FRONT

		THICKNESS					HARDNESS						
		RANGE ( 2.0 ---- 3.0 )mm					RANGE ( 1.0 ----- 6.0 ) kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	12:50 PM	2.60	2.63	2.61	2.71	2.78	4.2	4.1	3.0	3.7	4.7	P	Scm ASR
11/19/07	1:00 PM	2.57	2.58	2.60	2.60	2.74	5.1	5.1	3.6	4.3	4.6	P	UM
11/19/07	2:10 PM	2.64	2.60	2.60	2.63	2.61	5.3	5.0	4.8	4.3	4.1	P	Scm
<del>11/19/07</del> 11/20/07	7:45 AM	2.72	2.65	2.70	2.71	2.69	4.3	4.8	4.6	4.0	4.2	P	UM
11/20/07	8:45 AM	2.72	2.75	2.68	2.68	2.67	3.5	4.5	3.6	3.5	4.5	P	mmr ASR
11/20/07	9:50 AM	2.69	2.72	2.69	2.76	2.70	4.8	4.0	4.3	5.0	5.2	P	mmr Scm
11/20/07	11:00 AM	2.66	2.68	2.70	2.67	2.64	5.4	3.6	4.5	4.4	4.2	P	ASR
11/20/07	12:02 PM	2.67	2.68	2.73	2.62	2.68	4.7	3.9	4.5	5.0	4.0	P	Scm ASR
11/20/07	1:00 PM	2.62	2.61	2.67	2.68	2.67	4.9	4.4	4.4	4.6	4.8	P	UM
								Scm					
				N/A						11/20/07			

REV. BY ScmDATE 11/20/07

PLAINTIFFS' EXHIBITS 000026

COPY

p. 15 of 19  
11/20/07

AMIDE PHARMACEUTICAL, INC  
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

WEIGHT

BATCH 70924APRODUCT Digoxin Tablets 0.125 mg

COPY

PRESS.NO 67SIDE RearTHEO. 0.105gmRANGE 0.097 ---- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	12:00 PM	0.105	0.107	0.102	0.104	0.104	0.110	0.102	0.108	0.103	0.104	P	Scm
11/19/07	1:00 PM	0.103	0.105	0.104	0.103	0.105	0.102	0.103	0.102	0.103	0.104	P	Scm
11/19/07	2:10 PM	0.109	0.106	0.104	0.103	0.103	0.106	0.105	0.103	0.103	0.102	P	Scm
11/20/07	7:45 AM	0.102	0.108	0.102	0.101	0.104	0.104	0.108	0.104	0.106	0.110	P	Scm
11/20/07	8:45 AM	0.108	0.101	0.107	0.101	0.104	0.105	0.105	0.104	0.103	0.105	P	Scm
11/20/07	9:50 AM	0.106	0.104	0.108	0.105	0.104	0.106	0.105	0.106	0.107	0.105	P	Scm
11/20/07	11:00 AM	0.106	0.103	0.104	0.104	0.105	0.109	0.103	0.106	0.105	0.104	P	Scm
11/20/07	12:00 PM	0.105	0.104	0.106	0.105	0.104	0.110	0.107	0.105	0.105	0.105	P	Scm
11/20/07	1:00 PM	0.102	0.103	0.105	0.105	0.104	0.104	0.103	0.106	0.104	0.105	P	Scm
								Scm					
					N/A			11/20/07					

REV ScmDATE 11/20/07

11/26/11  
11/27/08

## QA IN-PROCESS COMPRESSION OVER SHEET DATA SHEET

THICKNESS/ HARDNESS

PRODUCT Digoxin Tablets 0.125 mg

PRESS NO 67

SIDE Rear

COPY

Batch 70924A

[illegible]REV. BY Scm

DATE 11/20/57

AMIDE PHARMACEUTICAL, INC.  
QA IN PROCESS COMPRESSION OVERCHECK DATA SHEET

COPY

## APPEARANCE

PRODUCT Digoxin Tablets 0.125 mgBatch 70924A

PRESS NO. <u>67</u>					
DATE	TIME	APPEARANCE-FRONT	APPEARANCE-REAR	DISP	BY
11/17/07	4:25pm	A	A	P	Scm
11/18/07	7:20am	A	A	P	Scm
11/18/07	8:20am	A	A	P	Scm
11/18/07	11:30am	A	A	P	Scm
11/18/07	12:30pm	A	A	P	Scm
11/18/07	1:30pm	A	A	P	Scm
11/18/07	2:30pm	A	A	P	Scm
11/18/07	3:30pm	A	A	P	Scm
11/18/07	4:00pm	A	A	P	Scm
11/19/07	7:50am	A	A	P	Scm
11/19/07	8:50am	A	A	P	Scm
11/19/07	9:50am	A	A	P	Scm
11/19/07	11:00am	A	A	P	Scm
11/19/07	12:00pm	A	A	P	Scm
11/19/07	1:00pm	A	A	P	Scm
11/19/07	2:00pm	A	A	P	Scm
11/19/07	6:55pm	A	A	P	Scm
11/20/07	7:45am	A	A	P	Scm
11/20/07	8:45am	A	A	P	Scm
11/20/07	9:50am	A	A	P	Scm
11/20/07	11:00am	A	A	P	Scm
11/20/07	12:00pm	A	A	P	Scm
11/20/07	1:00pm	A	A	P	Scm
N/A			Scm 11/20/07		

REV. BY Scm 11/20/07

Actavis Totowa LLC

## COMPRESSION DATA SHEET

Page 1 of 5

Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg Batch #: 70924A Date: 11/17/07 SPC11/18/07 11/11/10Tablet Press Id: 251 Hardness Tester Id: 251 Thickness Gauge Id: 967 Scale Id: 1156

Target Weight (1 Tablet): 105.0 mg

Thickness: 2.0 - 3.0 mm

Target Weight (10 Tablets): 1.050 g

Hardness: 1.0 - 6.0 KP

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

OF 7

Every 30 minutes, check ten (10) tablets for aggregate weight and appearance and three (3) tablets for hardness and thickness from each exit chute of the tablet press and compare results to the above product specifications. Record RPM of tablet press upon stabilization of press after every startup, and speed changes

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
	MIC	start	UP						SPG										
PM 3:20	1.066	OK	2.71	2.73	2.68	4.2	3.8	4.0	SPG	PM 3:20	1.062	OK	2.70	2.71	2.74	4.0	3.9	3.5	SPG
	Exit	sy	check						SPG										
	MIC	stop	For QA Approval						SPG										
	MIC	start	After QA Approval						SPG										
PM 4:10	1.055	OK	2.71	2.68	2.68	4.2	3.9	4.2	SPG	PM 4:10	1.065	OK	2.71	2.70	2.69	4.1	4.5	3.7	SPG
4:40	1.068	OK	2.69	2.73	2.68	3.8	4.6	4.0	SPG	4:40	1.049	OK	2.66	2.70	2.69	4.2	3.8	3.6	SPG
4:50	MIC	stop	For End of Shift						SPG										
	MIC	start	UP	11/18/07					AV										
Date	SPG 11/17/07					Comments:													
Time	PM 4:15																		
RPM	22																		

\*App = Appearance

&lt;14504-08&gt;



Actavis Totowa LLC

## COMPRESSION DATA SHEET

Page 2 of 5

Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924A

Date: 11/18/07

Target Weight (10 Tablets): 1.050 g

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
7:30 AM	1.066	OK	2.73	2.68	2.71	4.0	4.0	4.2	AV	7:30 AM	1.040	OK	2.68	2.70	2.67	3.1	3.4	3.7	AV
8:00	1.055	OK	2.71	2.68	2.65	3.3	3.8	4.2	AV	8:00	1.051	OK	2.69	2.71	2.68	3.9	3.6	3.7	AV
8:30	1.043	OK	2.69	2.62	2.65	3.8	4.2	4.0	AV	8:30	1.047	OK	2.68	2.73	2.70	4.3	3.7	4.0	AV
9:00	1.044	OK	2.67	2.66	2.67	3.9	4.0	3.7	AV	9:00	1.047	OK	2.64	2.65	2.65	3.6	4.0	4.3	AV
9:30	1.048	OK	2.69	2.67	2.68	3.8	4.4	4.0	AV	9:30	1.048	OK	2.67	2.66	2.66	4.0	4.0	4.1	AV
10:00	1.052	OK	2.64	2.68	2.69	4.7	4.3	4.2	AV	10:00	1.051	OK	2.73	2.67	2.69	4.5	4.3	3.8	AV
10:30	1.055	OK	2.70	2.65	2.70	3.7	3.7	4.4	AV	10:30	1.043	OK	2.64	2.63	2.68	4.3	3.9	3.9	AV
11:00	1.043	OK	2.69	2.64	2.66	4.2	4.1	4.7	AV	11:00	1.064	OK	2.69	2.67	2.69	4.8	4.1	4.5	AV
11:30	1.052	OK	2.69	2.62	2.62	4.3	3.8	3.8	AV	11:30	1.054	OK	2.64	2.65	2.64	4.7	4.6	4.3	AV
12:00 PM	1.047	OK	2.63	2.66	2.65	4.0	4.1	4.3	AV	12:00 PM	1.054	OK	2.66	2.67	2.65	4.4	4.3	4.5	AV
12:30	1.042	OK	2.64	2.65	2.63	4.1	5.0	4.1	AV	12:30	1.051	OK	2.63	2.68	2.64	4.0	4.2	4.1	AV
12:50	m/c stop Break								AV										
1:10	1.048	OK	2.63	2.64	2.63	4.2	4.1	3.9	AV	1:10	1.045	OK	2.71	2.62	2.61	3.6	4.2	4.2	AV
1:40	1.047	OK	2.66	2.68	2.66	4.4	4.2	4.5	AV	1:40	1.045	OK	2.66	2.65	2.66	3.9	4.0	3.9	AV
Date	11/18/07					Comments:													
Time	7:40 AM																		
RPM	22																		

\*App = Appearance

&lt;14504-08&gt;

Actavis Totowa LLC

## COMPRESSION DATA SHEET

Page 3 of 5

Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924A

Date: 11/18/07

Target Weight (10 Tablets): 1.050 g

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
2:10 PM	1.055	OK	2.67	2.71	2.69	3.9	4.3	4.6	AV	2:10 PM	1.046	OK	2.67	2.66	2.64	4.3	3.9	3.6	AV
2:40	1.041	OK	2.61	2.66	2.64	4.1	3.7	4.3	AV	2:40	1.053	OK	2.67	2.71	2.70	4.0	4.4	4.1	AV
3:10	1.067	OK	2.69	2.67	2.66	4.3	4.1	4.2	SCR	3:10	1.066	OK	2.69	2.68	2.66	4.3	4.0	4.0	SCR
3:40	1.060	OK	2.63	2.66	2.64	4.1	4.0	3.8	SCR	3:40	1.055	OK	2.65	2.60	2.63	4.8	4.1	4.7	SCR
4:10	1.054	OK	2.68	2.65	2.61	4.0	3.8	4.1	SCR	4:10	1.061	OK	2.68	2.70	2.66	4.0	4.4	4.1	SCR
4:40	1.058	OK	2.66	2.70	2.69	4.1	4.4	3.9	SCR	4:40	1.065	OK	2.61	2.66	2.68	4.3	4.4	4.0	SCR
4:52	m/c STOP end of shift								SCR										
AV 11/18/07	m/c	start up				11/19/07			AV										
7:50 AM	1.065	OK	2.77	2.72	2.74	3.8	3.9	3.9	AV	7:50 AM	1.066	OK	2.74	2.72	2.74	3.7	4.2	4.3	AV
8:20	1.060	OK	2.74	2.68	2.66	4.3	4.2	3.8	AV	8:20	1.059	OK	2.69	2.73	2.67	4.1	4.0	3.9	AV
8:50	1.054	OK	2.68	2.72	2.65	3.7	3.8	4.3	AV	8:50	1.063	OK	2.68	2.69	2.67	4.3	4.1	4.3	AV
9:20	1.056	OK	2.71	2.72	2.69	4.1	4.0	3.7	AV	9:20	1.064	OK	2.68	2.73	2.69	4.1	4.2	3.9	AV
9:50	1.068	OK	2.70	2.68	2.69	4.2	4.2	4.4	AV	9:50	1.054	OK	2.68	2.64	2.67	4.0	3.9	4.0	AV
10:20	1.053	OK	2.68	2.68	2.71	3.7	4.4	4.0	AV	10:20	1.068	OK	2.70	2.68	2.72	4.6	4.2	4.3	AV
Date	AV 11/18/07					Comments:													
Time	2:20 PM																		
RPM	22																		

\*App = Appearance

&lt;14504-Q8&gt;



Actavis Totowa LLC

## COMPRESSION DATA SHEET

Page 4 of 5

Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924A

Date: 11/19/07

Target Weight (10 Tablets): 1.050 g

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
10:28 AM	m/c	STOP	FOR Break						AV										
11:00	1.068	OK	2.66	2.70	2.68	4.0	4.0	4.7	AV	11:00	1.069	OK	2.70	2.72	2.72	5.1	4.1	4.7	AV
11:30	1.042	OK	2.66	2.64	2.64	4.0	4.1	4.4	AV	11:30	1.060	OK	2.66	2.71	2.65	4.4	3.8	3.9	AV
12:00 PM	1.041	OK	2.63	2.66	2.62	4.8	4.2	4.8	AV	12:00 PM	1.062	OK	2.67	2.68	2.65	4.6	4.2	4.3	AV
12:30	1.051	OK	2.64	2.65	2.64	4.7	4.4	4.3	AV	12:30	1.041	OK	2.65	2.66	2.69	4.2	3.7	4.5	AV
1:00	1.041	OK	2.62	2.65	2.66	4.4	4.3	4.4	AV	1:00	1.048	OK	2.65	2.68	2.71	4.5	3.9	4.0	AV
1:28	m/c	STOP	FOR Lunch Break						AV										
2:10	1.056	OK	2.68	2.70	2.66	5.1	4.6	5.1	AV	2:10	1.052	OK	2.68	2.74	2.69	3.9	4.0	4.2	AV
2:40	1.064	OK	2.68	2.65	2.65	4.0	4.4	4.6	AV	2:40	1.054	OK	2.70	2.68	2.69	4.5	4.5	4.3	AV
3:10	1.065	OK	2.69	2.67	2.68	4.4	4.2	5.1	AV	3:10	1.059	OK	2.69	2.68	2.65	4.7	4.9	4.8	AV
3:40	1.055	OK	2.64	2.66	2.68	4.1	4.4	3.9	AV	3:40	1.061	OK	2.71	2.75	2.70	3.8	4.3	4.1	AV
3:55	m/c stop								pmc										
6:20 PM	1.068	OK	2.67	2.71	2.72	4.3	4.7	4.2	pmc	6:20 PM	1.066	OK	2.72	2.70	2.73	4.2	4.5	4.1	pmc
6:50	1.066	OK	2.68	2.69	2.70	4.4	4.5	4.7	pmc	6:50	1.060	OK	2.66	2.68	2.67	4.4	4.3	4.5	pmc
Date	11/19/07					Comments:													
Time	11:15 AM																		
RPM	22																		

\*App = Appearance

&lt;14504-08&gt;

Actavis Totowa LLC

## COMPRESSION DATA SHEET

Page 5 of 5

Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924A

Date: 11/19/07  
11/20/07

Target Weight (10 Tablets): 1.050 g

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
7:00 <sup>PM</sup>	m/c	stop for	Lunch Time						PMG										
7:25 <sup>AM</sup>	1.062	OK	2.72	2.71	2.68	4.3	3.9	4.6	PMG	7:25 <sup>AM</sup>	1.052	OK	2.65	2.66	2.67	4.0	4.3	3.9	PMG
7:52	m/c	stop	End of the day						PMG										
	m/c	start	11/20/07						AV										
7:50 <sup>AM</sup>	1.058	OK	2.71	2.71	2.72	3.5	4.2	3.6	AV	7:50 <sup>AM</sup>	1.053	OK	2.75	2.69	2.73	3.5	3.7	3.6	AV
8:20	1.058	OK	2.65	2.67	2.69	3.9	4.3	4.3	AV	8:20	1.057	OK	2.69	2.68	2.75	4.2	4.3	3.7	AV
8:50	1.048	OK	2.69	2.71	2.68	4.0	3.4	3.8	AV	8:50	1.046	OK	2.69	2.68	2.69	3.9	3.6	4.0	AV
9:20	1.046	OK	2.68	2.63	2.61	4.6	4.8	4.6	AV	9:20	1.054	OK	2.64	2.66	2.65	4.5	4.6	4.4	AV
9:50	1.061	OK	2.69	2.71	2.70	4.3	4.0	4.0	AV	9:50	1.059	OK	2.70	2.69	2.68	3.9	4.3	3.7	AV
10:20	1.053	OK	2.68	2.67	2.67	3.8	3.7	4.2	AV	10:20	1.046	OK	2.64	2.66	2.64	3.9	4.2	3.9	AV
10:28	m/c	stop	For break						AV										
11:00	1.047	OK	2.68	2.69	2.67	4.0	4.6	4.0	AV	11:00	1.036	OK	2.69	2.65	2.65	3.5	4.0	3.7	AV
11:25	m/c	stop																	
Date	PMG 11/19/07	AV 11/20/07				Comments:													
Time	7:30 <sup>PM</sup>	8:15 <sup>AM</sup>																	
REF	22	22																	

\*App = Appearance

&lt;14504-QB&gt;

## Amide Pharmaceutical, Inc.

## QA In-Process Compression Start Up Data Sheet

COPY 34/167  
1.32.6/167  
JMB

Product: <b>Digoxin Tablets, 0.125 mg</b>		Batch Number: <b>70924A</b>
Number of Stations: <b>45</b>		Side: <b>FRONT</b>
Appearance: <b>A</b>		MPR #: <b>14 504-08</b>
Specifications		
Weight (Th. 0.105 g) (0.097 - 0.113) g	Thickness (2.00 - 3.00) mm	Hardness (1.0 - 6.0) kp
Compression Data Sheet signed / Equipment cleared		Verified By: <b>ASR / Scm</b> Date: <b>11/17/07 11/17/07</b>

	Weight	Thickness	Hardness
1	0.102	2.75	3.5
2	0.106	2.78	3.8
3	0.104	2.69	3.2
4	0.108	2.73	3.4
5	0.105	2.72	4.3
6	0.107	2.76	3.4
7	0.105	2.75	3.6
8	0.105	2.78	4.0
9	0.107	2.72	3.8
10	0.109	2.72	3.5
11	0.107	2.75	4.2
12	0.108	2.72	3.9
13	0.104	2.76	4.3
14	0.108	2.73	3.4
15	0.110	2.75	3.2
16	0.105	2.77	3.2
17	0.109	2.80	4.1
18	0.105	2.78	3.9
19	0.107	2.74	3.8
20	0.106	2.76	3.9
21	0.105	2.75	3.8
22	0.108	2.72	3.9
23	0.107	2.69	4.0
24	0.107	2.73	3.7
25	0.108	2.74	3.7

	Weight	Thickness	Hardness
26	0.107	2.69	3.6
27	0.104	2.69	3.4
28	0.101	2.74	3.8
29	0.105	2.65	3.5
30	0.109	2.70	4.1
31	0.102	2.69	3.5
32	0.109	2.71	3.7
33	0.104	2.70	3.6
34	0.105	2.73	3.9
35	0.103	2.72	3.8
36	0.105	2.68	4.2
37	0.101	2.70	4.0
38	0.104	2.69	3.7
39	0.111	2.71	3.4
40	0.105	2.71	3.4
41	0.105	2.72	3.6
42	0.110	2.70	3.5
43	0.106	2.68	4.0
44	0.109	2.69	3.9
45	0.104	2.71	3.7
46	N/A		
47			
48			
49			
50			

Disposition: Pass  
 Analyzed By: ASR / Scm  
 Reviewed By: Scm

Time: 4:05 PM  
 Date: 11/17/07 11/17/07  
 Date: 11/20/07

Comments:

N/A Scm 11/20/07

Digoxin 0.125 mg Data F.00

## Amide Pharmaceutical, Inc.

## QA In-Process Compression Start Up Data Sheet

Product: **Digoxin Tablets, 0.125 mg** Batch Number: 70924A

Press #: 71 Number of Stations: 45 Side: **REAR**

Appearance: A MPR #: 70924A

Specifications		
Weight (Th. 0.105 g) (0.097 - 0.113) g	Thickness (2.00 - 3.00) mm	Hardness (1.0 - 6.0) kp

Compression Data Sheet signed / Equipment cleared Verified By: ASR/Scm Date: 11/17/07 11/17/07

	Weight	Thickness	Hardness
1	0.108	2.74	4.1
2	0.107	2.75	4.1
3	0.106	2.73	4.1
4	0.106	2.75	4.7
5	0.108	2.74	3.8
6	0.109	2.75	4.2
7	0.110	2.72	3.9
8	0.107	2.79	3.9
9	0.106	2.74	3.7
10	0.107	2.74	3.9
11	0.110	2.77	4.0
12	0.109	2.72	3.8
13	0.109	2.70	4.0
14	0.110	2.74	4.1
15	0.108	2.71	4.3
16	0.106	2.76	4.0
17	0.107	2.71	3.8
18	0.109	2.70	4.1
19	0.108	2.76	4.6
20	0.107	2.71	4.1
21	0.108	2.72	4.0
22	0.110	2.72	3.9
23	0.107	2.71	4.5
24	0.110	2.73	4.3
25	0.107	2.71	4.1

	Weight	Thickness	Hardness
26	0.110	2.72	4.3
27	0.108	2.76	4.1
28	0.107	2.71	4.5
29	0.108	2.74	3.8
30	0.107	2.74	4.4
31	0.110	2.75	4.4
32	0.109	2.73	4.3
33	0.108	2.71	3.7
34	0.108	2.73	4.1
35	0.105	2.73	4.2
36	0.107	2.73	4.4
37	0.108	2.68	3.9
38	0.105	2.72	4.1
39	0.107	2.75	3.7
40	0.107	2.72	4.2
41	0.108	2.74	4.1
42	0.109	2.74	4.2
43	0.108	2.75	4.0
44	0.110	2.74	4.3
45	0.110	2.73	3.9
46	N/A		
47			
48			
49			
50			

Disposition: Pass

Analyzed By: ASR/Scm

Reviewed By: Scm

Time: 4:05 PM

Date: 11/17/07 11/17/07

Date: 11/20/07

Comments: N/A Scm 11/20/07

Digoxin 0.125 mg.Data.R.00

AMIDE PHARMACEUTICAL, INC  
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

WEIGHT

BATCH 70924APRODUCT Digoxin Tablets 0.125 mg

COPY

PRESS.NO 71SIDE FrontTHEO. 0.105gmRANGE 0.097 --- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:35 am	0.108	0.107	0.107	0.106	0.107	0.104	0.107	0.107	0.108	0.106	P	Sam ASR
11/18/07	8:25 am	0.105	0.106	0.107	0.105	0.104	0.107	0.109	0.104	0.105	0.105	P	Sam ASR
11/18/07	9:15 am	0.107	0.103	0.106	0.103	0.106	0.106	0.107	0.104	0.102	0.102	P	Sam ASR
11/18/07	10:25 am	0.106	0.104	0.105	0.104	0.105	0.103	0.104	0.105	0.103	0.104	P	Sam ASR
11/18/07	11:25 am	0.103	0.107	0.103	0.105	0.104	0.109	0.102	0.108	0.109	0.103	P	Sam ASR
11/18/07	12:25 pm	0.103	0.103	0.104	0.106	0.105	0.105	0.104	0.103	0.105	0.105	P	Sam ASR
11/18/07	1:25 pm	0.103	0.101	0.105	0.104	0.106	0.103	0.102	0.107	0.102	0.105	P	Sam ASR
11/18/07	2:25 pm	0.104	0.103	0.105	0.104	0.105	0.105	0.103	0.104	0.103	0.106	P	Sam ASR
11/18/07	3:25 pm	0.105	0.105	0.108	0.102	0.107	0.106	0.103	0.104	0.107	0.107	P	Kee Sam
11/18/07	4:10 pm	0.104	0.106	0.108	0.105	0.107	0.105	0.106	0.107	0.106	0.106	P	Sam ASR
11/19/07	8:00 am	0.104	0.107	0.107	0.107	0.107	0.103	0.106	0.108	0.107	0.107	P	Sam ASR
11/19/07	9:00 am	0.105	0.104	0.111	0.105	0.107	0.104	0.107	0.109	0.107	0.106	P	Sam ASR

REV SamDATE 11/20/07

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Amide Pharmaceutical, Inc.  
QA IN - PROCESS COMPRESSION OVER CHECK DATA SHEET

THICKNESS / HARDNESS

PRODUCT Digoxin Tablets 0.125mg

COPY

BATCH 70 924APRESS NO 71SIDE FRONT

		THICKNESS					HARDNESS						
		RANGE ( 2.0 ---- 3.0 )mm					RANGE ( 1.0 ----- 6.0 ) kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:35 am	2.68	2.68	2.72	2.75	2.73	3.6	4.2	4.2	3.8	4.1	P	Sam ASR
11/18/07	8:25 pm	2.70	2.67	2.70	2.72	2.70	4.5	4.1	4.2	3.7	4.0	P	Sam ASR
11/18/07	9:15 pm	2.63	2.73	2.66	2.79	2.71	3.8	3.7	3.9	3.8	4.0	P	Sam ASR
11/18/07	10:25 am	2.66	2.68	2.66	2.72	2.71	3.4	3.4	4.0	4.8	4.5	P	Sam ASR
11/18/07	11:25 pm	2.64	2.66	2.63	2.68	2.69	4.2	4.1	4.5	4.2	4.7	P	Sam ASR
11/18/07	12:25 pm	2.65	2.62	2.62	2.64	2.69	4.2	4.4	3.5	4.2	3.7	P	Sam ASR
11/18/07	1:25 pm	2.66	2.65	2.65	2.64	2.71	3.8	3.9	3.9	3.8	4.0	P	Sam ASR
11/18/07	2:25 pm	2.63	2.71	2.67	2.69	2.69	4.2	4.5	4.7	3.4	4.2	P	Sam ASR
11/18/07	3:25pm	2.68	2.72	2.69	2.70	2.67	4.6	4.8	4.3	4.1	4.3	P	Jae
11/18/07	4:10 pm	2.69	2.67	2.70	2.68	2.71	4.9	4.7	4.7	4.9	3.8	P	Sam
11/19/07	8:00 am	2.73	2.72	2.70	2.82	2.77	4.0	4.1	4.0	4.0	4.2	P	ASR Sam
11/19/07	9:00 am	2.67	2.71	2.71	2.66	2.78	3.9	4.1	4.3	3.7	3.7	P	ASR Sam

REV. BY SamDATE 11/20/07

PLAINTIFFS' EXHIBITS 000038

COPY

11/18/07

11/19/07

AMIDE PHARMACEUTICAL, INC  
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

WEIGHT

BATCH 70924A

COPY

PRODUCT Digoxin Tablets 0.125 mgPRESS.NO. 71SIDE RearTHEO. 0.105gmRANGE 0.097 --- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:35 AM	0.106	0.105	0.102	0.101	0.108	0.105	0.102	0.106	0.102	0.105	P	Scm ASR
11/18/07	8:25 AM	0.105	0.102	0.105	0.104	0.108	0.104	0.103	0.102	0.106	0.104	P	Scm ASR
11/18/07	9:15 AM	0.106	0.108	0.105	0.106	0.104	0.106	0.107	0.108	0.105	0.104	P	Scm ASR
11/18/07	10:25 AM	0.105	0.105	0.106	0.103	0.104	0.105	0.105	0.106	0.104	0.103	P	Scm ASR
11/18/07	11:25 AM	0.108	0.106	0.109	0.102	0.105	0.108	0.107	0.105	0.104	0.107	P	Scm ASR
11/18/07	12:25 PM	0.105	0.102	0.106	0.107	0.103	0.104	0.105	0.103	0.105	0.102	P	Scm ASR
11/18/07	1:25 PM	0.106	0.104	0.103	0.103	0.105	0.104	0.105	0.101	0.105	0.106	P	Scm ASR
11/18/07	2:25 PM	0.105	0.106	0.110	0.105	0.107	0.106	0.105	0.104	0.106	0.107	P	ASR Scm
11/18/07	3:25 PM	0.105	0.105	0.106	0.104	0.106	0.106	0.104	0.105	0.106	0.103	P	KL
11/18/07	4:10 PM	0.108	0.107	0.108	0.107	0.107	0.106	0.107	0.106	0.107	0.104	P	Scm
11/19/07	8:00 AM	0.109	0.105	0.108	0.106	0.106	0.106	0.106	0.107	0.108	0.107	P	ASR Scm
11/19/07	9:00 AM	0.107	0.105	0.106	0.109	0.106	0.107	0.108	0.105	0.107	0.107	P	ASR Scm

REV ScmDATE 11/20/07

PLAINTIFFS' EXHIBITS 000039

## QA IN-PROCESS COMPRESSION OVERSIGHT DATA SHEET

THICKNESS/ HARDNESS

PRODUCT Digoxin Tablets 0.125 mg

Batch 70924A

PRESS NO 71

SIDE Rear

COPY

		THICKNESS					HARDNESS						
		RANGE (2.0 ---- 3.0)mm					RANGE (1.0---6.0)kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:25 AM	2.67	2.67	2.70	2.73	2.68	3.1	3.1	3.6	3.6	3.7	P	Scm ASR
11/18/07	8:25 AM	2.64	2.65	2.64	2.63	2.67	3.2	4.3	3.6	4.0	3.9	P	ASR Scm
11/18/07	9:15 AM	2.68	2.69	2.69	2.71	2.69	3.9	4.7	4.1	4.1	4.0	P	ASR Scm
11/18/07	10:25 AM	2.67	2.74	2.69	2.66	2.68	4.5	4.6	4.5	3.9	4.2	P	Scm ASR
11/18/07	11:25 AM	2.70	2.70	2.72	2.71	2.71	4.9	4.6	4.4	4.3	4.4	P	ASR Scm
11/18/07	12:25 PM	2.68	2.72	2.66	2.66	2.66	4.0	4.2	4.2	4.3	3.6	P	ASR Scm
11/18/07	1:25 PM	2.66	2.62	2.69	2.68	2.66	4.3	3.6	4.3	3.7	4.1	P	Scm ASR
11/18/07	2:25 PM	2.68	2.68	2.64	2.65	2.65	4.3	4.7	4.2	4.5	4.3	P	Scm ASR
11/18/07	3:25 PM	2.65	2.69	2.64	2.69	2.66	5.4	4.5	4.5	4.6	4.7	P	Scm ASR
11/18/07	4:10 PM	2.67	2.68	2.68	2.70	2.68	4.4	4.2	4.8	4.5	4.2	P	Scm ASR
11/19/07	8:00 AM	2.70	2.72	2.74	2.67	2.70	4.1	3.8	4.1	4.0	4.2	P	ASR Scm
11/19/07	9:00 AM	2.70	2.72	2.71	2.70	2.73	4.1	4.5	4.3	4.6	4.0	P	ASR Scm

REV. BY Sam

DATE 11/20/07

$\frac{29}{100} \times \frac{169}{100}$   
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AMIDE PHARMACEUTICAL, INC  
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

WEIGHT

BATCH 70924A  
702 ASR  
11/19/07

PRODUCT Digoxin Tablets 0.125 mg

COPY

PRESS.NO 71SIDE FrontTHEO. 0.105gmRANGE 0.097 ---- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	10:00 AM	0.105	0.106	0.106	0.104	0.109	0.107	0.108	0.104	0.107	0.107	P	ASR
11/19/07	11:10 AM	0.103	0.107	0.110	0.105	0.105	0.109	0.105	0.109	0.104	0.107	P	NUM
11/19/07	12:10 PM	0.103	0.105	0.102	0.106	0.105	0.103	0.102	0.104	0.106	0.105	P	ASR
11/19/07	1:10 PM	0.107	0.105	0.105	0.106	0.104	0.107	0.105	0.104	0.106	0.105	P	NUM
11/19/07	2:20 PM	0.105	0.106	0.107	0.107	0.106	0.105	0.104	0.105	0.107	0.107	P	Sam
11/19/07	3:25 PM	0.105	0.106	0.105	0.105	0.106	0.103	0.108	0.104	0.107	0.106	P	fe
11/19/07	6:25 PM	0.105	0.104	0.105	0.103	0.103	0.107	0.104	0.103	0.106	0.108	P	ASR
11/19/07	7:30 PM	0.108	0.104	0.109	0.105	0.106	0.108	0.107	0.106	0.104	0.105	P	ASR
11/20/07	7:55 AM	0.104	0.110	0.107	0.108	0.106	0.109	0.106	0.109	0.106	0.107	P	NUM
11/20/07	8:55 AM	0.105	0.103	0.101	0.109	0.107	0.108	0.105	0.107	0.107	0.108	P	ASR
11/20/07	9:55 AM	0.107	0.105	0.106	0.108	0.105	0.107	0.106	0.109	0.105	0.107	P	NUM
11/20/07	11:10 PM	0.102	0.109	0.108	0.106	0.102	0.104	0.105	0.109	0.107	0.103	P	ASR

REV SamDATE 11/20/07

46  
11/20/07  
ASR

Amide Pharmaceutical, Inc.  
QA IN - PROCESS COMPRESSION OVER CHECK DATA SHEET

THICKNESS / HARDNESS

PRODUCT Digoxin Tablets 0.125mgCOPY BATCH 70924APRESS NO 71SIDE FRONT

		THICKNESS					HARDNESS						
		RANGE ( 2.0 ---- 3.0 )mm					RANGE ( 1.0 ----- 6.0 ) kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	10:00 Am	2.66	2.69	2.68	2.71	2.70	4.1	3.7	4.7	4.1	3.9	P	Scm ASR
11/19/07	11:10 AM	2.67	2.67	2.66	2.67	2.67	3.4	4.7	4.1	4.5	3.7	P	UM
11/19/07	12:10 pm	2.66	2.70	2.64	2.70	2.66	4.2	3.9	4.2	4.5	4.1	P	Scm ASR
11/19/07	1:10 pm	2.67	2.68	2.67	2.66	2.66	4.6	4.6	4.7	4.9	4.4	P	UM
11/19/07	2:20 Pm	2.68	2.72	2.66	2.70	2.70	4.2	3.9	4.4	4.3	4.4	P	Scm
11/19/07	3:25 PM	2.69	2.67	2.66	2.63	2.67	4.4	4.7	4.2	4.4	4.2	P	ASR
11/19/07	6:25 pm	2.70	2.67	2.72	2.67	2.69	4.2	4.3	4.0	4.0	4.4	P	Scm ASR
11/19/07	7:30 pm	2.73	2.72	2.71	2.68	2.69	3.9	3.5	4.5	4.8	4.5	P	Scm ASR
11/20/07	7:55 Am	2.73	2.75	2.73	2.70	2.72	3.9	3.7	4.0	3.5	4.0	P	UM
11/20/07	8:55 Am	2.71	2.71	2.75	2.72	2.71	4.1	4.5	4.3	4.4	4.0	P	MMR ASR
11/20/07	9:55 AM	2.70	2.71	2.72	2.77	2.72	4.4	5.3	4.2	4.1	4.4	P	MMR
11/20/07	11:10 AM	2.69	2.70	2.74	2.68	2.70	4.3	3.6	4.4	4.2	4.4	P	Scm ASR

REV. BY ScmDATE 11/20/07

PLAINTIFFS' EXHIBITS 000042

AMIDE PHARMACEUTICAL, INC  
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

WEIGHT

BATCH 70924A

PRODUCT Digoxin Tablets 0.125 mg

COPY

PRESS.NO 71

SIDE Rear

THEO. 0.105gm

RANGE 0.097 --- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	10:00 AM	0.104	0.105	0.107	0.104	0.104	0.105	0.107	0.107	0.106	0.105	P	Sam ASR
11/19/07	11:10 AM	0.105	0.105	0.104	0.103	0.108	0.105	0.106	0.106	0.104	0.105	P	UM
11/19/07	10:10 PM	0.104	0.106	0.104	0.106	0.106	0.101	0.102	0.104	0.105	0.104	P	Sam ASR
11/19/07	1:10 PM	0.103	0.107	0.107	0.107	0.106	0.105	0.110	0.103	0.108	0.106	P	UM
11/19/07	2:20 PM	0.107	0.108	0.106	0.107	0.107	0.104	0.106	0.105	0.105	0.103	P	Sam
11/19/07	3:25 PM	0.104	0.104	0.108	0.104	0.105	0.105	0.104	0.107	0.103	0.106	P	te
11/19/07	6:25 PM	0.105	0.107	0.105	0.103	0.105	0.105	0.103	0.104	0.107	0.103	P	Sam ASR
11/19/07	7:30 PM	0.106	0.105	0.106	0.105	0.104	0.106	0.102	0.107	0.102	0.106	P	Sam ASR
11/20/07	7:55 AM	0.106	0.104	0.105	0.107	0.108	0.107	0.101	0.107	0.103	0.109	P	UM
11/20/07	8:55 AM	0.104	0.103	0.108	0.102	0.105	0.104	0.106	0.103	0.106	0.104	P	mm ASR
11/20/07	9:55 AM	0.105	0.107	0.106	0.104	0.108	0.105	0.107	0.106	0.104	0.105	P	mm ASR
11/20/07	11:10 AM	0.103	0.107	0.107	0.108	0.103	0.105	0.105	0.105	0.109	0.103	P	Sam ASR

REV Sam

DATE 11/20/57

42  
1-28-97  
PMB  
61/25/05

AMIDE PHARMACEUTICAL CO.  
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

THICKNESS/ HARDNESS

PRODUCT Digoxin Tablets 0.125 mgBatch 70924APRESS NO 71SIDE Rear

COPY

		THICKNESS					HARDNESS						
		RANGE (2.0 ----- 3.0)mm					RANGE (1.0---6.0)kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	10:00 Am	2.68	2.68	2.66	2.70	2.72	3.7	4.0	4.3	4.2	3.7	P	Sam ASR
11/19/07	11:10 Am	2.67	2.68	2.67	2.65	2.66	4.0	4.0	3.8	4.2	3.7	P	UM
11/19/07	12:10 Pm	2.63	2.66	2.66	2.70	2.63	3.8	3.7	3.5	4.4	4.1	P	Sam ASR
11/19/07	1:10 Pm	2.69	2.67	2.67	2.68	2.68	3.8	4.9	4.1	4.6	4.1	P	UM
11/19/07	2:20 Pm	2.68	2.69	2.71	2.66	2.65	3.7	3.9	4.6	4.0	4.7	P	Sam
11/19/07	3:25 Pm	2.64	2.68	2.65	2.68	2.66	4.4	3.8	4.2	4.2	4.0	P	ASR
11/19/07	6:25 Pm	2.69	2.69	2.69	2.70	2.74	5.0	3.7	4.2	4.0	4.5	P	Sam ASR
11/19/07	7:30 Pm	2.67	2.69	2.71	2.70	2.69	3.8	3.7	4.0	4.2	4.1	P	Sam ASR
11/20/07	7:55 Am	2.68	2.68	2.67	2.72	2.72	3.7	3.7	3.4	4.3	4.2	P	UM
11/20/07	8:55 Am	2.67	2.71	2.70	2.69	2.64	3.7	3.9	3.9	3.9	3.8	P	mmr ASR
11/20/07	9:55 Am	2.69	2.67	2.69	2.71	2.70	3.9	3.6	4.5	4.3	4.0	P	mmr
11/20/07	11:10 Am	2.68	2.70	2.72	2.72	2.70	4.8	4.7	4.4	5.0	4.4	P	Sam ASR

REV. BY SamDATE 11/20/07

COPY

11/20/07

11/20/07

Actavis Totowa LLC

*Attachment #3*  
*01/25/08*  
**FINISHED PRODUCT RELEASE - TEST REPORT**

*01/25/08*  
*01/25/08*

Product: Digoxin Tablets, USP 0.125 mg			
MOI #: 145	Revision #: 08	Product ID #: 145	Page 1 of 3
Prepared By: <i>Emerson Murphy</i>	Date: 03/19/07	Approved By: <i>J. Talbot</i> 04/04/07	Effective Date: 07/12/07

Batch # 70924A

TEST (Source)	SPECIFICATION	RESULT	REFERENCE Volume/Page/ Chemist/Date
Description (In-house):	Yellow, round bisected tablets, debossed "A 145" or "B 145" on the bisected side	Yellow round, bisected tablets debossed "B145" on the bisected side	0162/50 DII 11/23/07
Identification A (USP):	The R <sub>f</sub> value of the principal spot in the chromatogram of the sample solution corresponds to that of the standard solution.	conforms	0130/173 NPH 11/24/07
Identification B (USP):	The retention time of the major peak in the chromatogram of the sample solution corresponds to that of the standard solution obtained as directed in the HPLC assay test.	<p><u>RT (min)</u></p> <p>S+2 ≈ 11.0 min</p> <p>Assay ≈ 11.7 min</p> <p>conforms</p>	0045/1201 KHS 11.27.07

(✓) COMPLIES

( ) DOES NOT COMPLY

REVIEWED	
BY: <i>JCS</i>	DATE: 11/28/07

DATA APPROVAL	
By: <i>[Signature]</i>	Date: 11/28/07

Actavis Totowa LLC

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COPY

## FINISHED PRODUCT RELEASE - TEST REPORT

Product: Digoxin Tablets, USP 0.125 mg			
MOI #: 145	Revision #: 08	Product ID #: 145	Page 2 of 3
Prepared By: <i>[Signature]</i>	Date: 03/19/07	Approved By: <i>[Signature]</i> 04/04/07	Effective Date: 07/12/07

Batch # 70924A

TEST (Source)	SPECIFICATION	RESULT		REFERENCE Volume/Page/ Chemist/Date
Friability (In-house):	NMT 1.0%	i.e. 0.02 % 0.0 %		0045/12.0/ KHS/11.27.07
Assay by HPLC (USP):	90.0% - 105.0%	96.0 %		0045/12.0/ KHS/11.27.07
Uniformity of Dosage Units by Content Uniformity (USP):	Acceptance Value ≤ 15.0 % (Meets USP <905> requirements)	1. 97.8 %	6. 96.9 %	0162/50 Dil 11/23/07
		2. 98.4 %	7. 95.4 %	
		3. 95.6 %	8. 96.3 %	
		4. 98.1 %	9. 95.8 %	
		5. 97.2 %	10. 95.9 %	
		Acceptance Value: 4.4 %		
		Dissolution (USP):  Apparatus: 1 (Basket) Medium: 0.1N HCl, 500 mL Temp: 37.0°C ± 0.5°C RPM: 120 Time: 60 minutes	NLT 80% (Q) dissolved in 60 minutes	
2. 102 %	5. 101 %			
3. 97 %	6. 98 %			
Average: 99 %				

☒ COMPLIES☐ DOES NOT COMPLY

REVIEWED

By: *JCS* DATE: 11/28/07

DATA APPROVAL

By: *[Signature]*

Date: 11/28/07



Actavis Totowa LLC

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## FINISHED PRODUCT RELEASE - TEST REPORT

Product: Digoxin Tablets, USP 0.125 mg			
MOI #: 145	Revision #: 08	Product ID #: 145	Page 3 of 3
Prepared By: <i>Zamora Murphy</i>	Date: 03/19/07	Approved By: <i>Salbot</i> 03/22/07	Effective Date: 07/12/07

Batch # 70924A
----------------

TEST (Source)	SPECIFICATION	RESULT	REFERENCE Volume/Page/ Chemist/Date
Related Substances (In-house):			0045   1201 KHS   11-27-07
Digoxigenin:	NMT 2.0%	EE KHS 11/27/07 <del>0.35</del> 0.37 %	
Digoxigenin Bisdigitoxoside:	NMT 2.0%	0.34 %	
Gitoxin:	NMT 3.0%	Not detected	01301173 MFM 11/24/07

<input checked="" type="checkbox"/> COMPLIES	<input type="checkbox"/> DOES NOT COMPLY
--	--

REVIEWED	
BY: <i>JCS</i>	DATE: 11/28/07

DATA APPROVAL	
By: <i>[Signature]</i>	Date: 11/28/07

Confidential

PLAINTIFFS' EXHIBITS 000047

ACTAV 000002603

Actavis Totowa LLC

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Page 18 of 24

MPR #: 14504	Rev #: 08	Effective Date: 6/16/06	Batch #: 70924A
Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)			
Batch Size: 4,800,000 Tablets			

11/25/08

OPERATING INSTRUCTIONS SECTION III  
TABLET COMPRESSION MACHINE SET-UP

COPY

1. Check the required debossing for Amide or Bertek before issuing this part of the batch record and cross out the section of the batch record for the other debossing in Step # 2, Page # 18 and Step # 2, Page # 19.

AMIDE ~~( )~~ K.V.P 11/12/07 BERTEK (✓)

Done By: K.V.P	Date: 11/12/07	Checked By: K.D	Date: 11/16/07
----------------	----------------	-----------------	----------------

2. Install the following Punch and Die Set:

AMIDE:

Punch Set	Box #	Description
Upper Punch	44, 44A	1/4" Flat bevel round bisect punches embossed "A145"
Lower Punch	44, 44A	1/4" Flat bevel round punches
Die Set	44, 44A	1/4" round dies

~~K.V.P 11/12/07~~

BERTEK:

Punch Set	Box #	Description
Upper Punch	135, 138, 189	1/4" Flat bevel round bisect punches embossed "B145"
Lower Punch	44, 44A, 135, 138, 189	1/4" Flat bevel round punches
Die Set	44, 44A, 135, 138, 189	1/4" round dies

NOTE: When two to five consecutive batches of DIGOXIN TABLETS, USP 0.125 mg are compressed, record "N/A" ("Not Applicable") for the second to fifth batch in the Done By and Checked By sections.

Done By: C.S	Date: 11/16/07	Checked By: AV	Date: 11/16/07
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**Actavis Totowa LLC**

MPR #: 14504	Rev #: 08	Effective Date: <u>6/16/06</u>	Batch #: <u>70924A</u>
Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)			
Batch Size: 4,800,000 Tablets			

OPERATING INSTRUCTIONS SECTION IV  
COMPRESSION

COPY

CAUTION: PLEASE USE GLOVES AND PROTECTIVE MASKS DURING OPERATION.  
NOTIFY THE SUPERVISOR IMMEDIATELY IF YOU HAVE A HEADACHE, FEEL WEAK  
OR PALPITATING.

1. Inspect for cleanliness of Production Room # 119, 120 and the following compression equipment.

Utensils (Stainless Steel Scoops, etc.)

Tablet Press #: 67 Mfr. & Model: Stokes BB2 # of Stations: 45  
Deduster(s) #: 121 Scale #: 940 Metal Detector #: 583

Tablet Press #: 71 Mfr. & Model: Stokes BB2 # of Stations: 45  
Deduster(s) #: 120 Scale #: 982 Metal Detector #: 582

Check the Production Room and Equipment Usage and Cleaning Logs for previous cleaning documentation, except utensils and scales.

ROOM #	DONE BY	DATE	QA APPROVAL BY	DATE
119	<u>SPG</u>	<u>11/17/07</u>	<u>ASR / UM</u>	<u>11/17/07</u>
120	<u>SPG</u>	<u>11/17/07</u>	<u>ASR / UM</u>	<u>11/17/07</u>

2. Compress tablets with the following characteristics:

Description:

- ☐ AMIDE: Yellow, round tablets, and imprinted with 'A 145' on the scored side of the tablet. N/A KVP 11/12/07  
☒ BERTEK: Yellow, round tablets, and imprinted with B 145 on the scored side of the tablet.

Target Weight (1 Tablet):	105.0 mg
Target Weight (10 Tablets):	1.050 g
Weight Range (10 Tablets):	1.019 - 1.082 g
Thickness:	2.0 - 3.0 mm
Hardness:	1.0 - 6.0 KP
Tablet Press Speed:	14 - 28 rpm

After the specifications are met, record the final values for the tablet weights, thickness, and hardness and indicate "Start-Up" on the Compression Data Sheet.

COPY

## Actavis Totowa LLC

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MPR #: 14504 Rev #: 08 Effective Date: 6/16/06

Batch #:

Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)

Batch Size: 4,800,000 Tablets

70924A

COMPRESSION

COPY

After QA approval, compress the tablets with the above listed characteristics. Monitor the weight, hardness, and thickness at least every thirty (30) minutes and record the results onto the In-Process Compression Data Sheet.

MACHINE #	DONE BY	CHECKED BY	DATE	QA APPROVAL BY	DATE
67	SPG	SMP	11/17/07	Scm	11/17/07
71	SPG	SMP	11/17/07	ASK / Scm	11/17/07

3. Weigh the filled containers of tablets and record the gross and net weights on the "Container ID Label - Compressed Tablets" for each container and in the appropriate rows below.

m/c#	CNTNR. #	SCALE #	GROSS (kg)	TARE (kg)	NET (kg)	WEIGHED BY	DATE
67	1	940	16.00	1.00	15.00	AV	11/18/07
71	2	982	16.10	1.10	15.00	AV	11/18/07
67	3	940	16.02	1.02	15.00	AV	11/18/07
71	4	982	16.02	1.02	15.00	AV	11/18/07
67	5	940	16.10	1.10	15.00	AV	11/18/07
71	6	982	16.10	1.10	15.00	AV	11/18/07
67	7	940	16.02	1.02	15.00	AV	11/18/07
71	8	982	16.10	1.10	15.00	AV	11/18/07
67	9	940	16.02	1.02	15.00	SKR	11/18/07
71	10	982	16.00	1.00	15.00	AV	11/18/07
67	11	940	16.00	1.00	15.00	SKR	11/18/07
71	12	982	<del>16.10</del> 16.00	1.10	15.00	AV	11/18/07
67	13	940	16.00	1.00	15.00	AV	11/19/07

AV  
11/18/07

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Actavis Totowa LLC

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MPR #: 14504 Rev #: 08 Effective Date: 6/15/06

Batch #:

Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)

Batch Size: 4,800,000 Tablets

70924A

COMPRESSION

COPY

mkt	CNTNR. #	SCALE #	GROSS (kg)	TARE (kg)	NET (kg)	WEIGHED BY	DATE
71	14	982	16.10	1.10	15.00	SKL	11/18/07
67	15	940	16.00	1.00	15.00	AV	11/19/07
71	16	982	16.10	1.10	15.00	SKL	11/18/07
67	17	940	16.02	1.02	15.00	AV	11/19/07
71	18	982	16.10	1.10	15.00	AV	11/19/07
67	19	940	16.10	1.10	15.00	AV	11/19/07
71	20	982	16.10	1.10	15.00	AV	11/19/07
67	21	940	16.10	1.10	15.00	AV	11/19/07
71	22	982	16.10	1.10	15.00	AV	11/19/07
71	23	982	16.10	1.10	15.00	AV	11/19/07
71	24	982	16.10	1.10	15.00	AV	11/19/07
71	25	982	16.12	1.12	15.00	AMS	11/19/07
71	26	982	16.10	1.10	15.00	AV	11/19/07
71	27	982	16.10	1.10	15.00	AV	11/20/07
67	28	982	16.10	1.10	15.00	AV	11/20/07
67	29	940	16.10	1.10	15.00	AV	11/20/07
71	30	982	16.02	1.02	15.00	AV	11/20/07
67	31	940	16.10	1.10	15.00	AV	11/20/07
67	32	940	16.10	1.10	15.00	AV	11/20/07
67	33	940	16.02	1.02	15.00	AV	11/20/07
67	34	940	5.24 16.00	1.00	4.24 15.00	AV	11/20/07
TOTAL					499.24	AV	11/20/07

Actavis Totowa LLC

COPY

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MPR #: 14504 Rev #: 08 Effective Date: 6/16/06

Batch #:

Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)

Batch Size: 4,800,000 Tablets

70924A

COMPRESSION

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4. Weigh the blend waste, if any, and tablet rejects in the Production Room # 119, +10 120, 1.56 kg.

AV 11/20/07

Also, weigh the total quantity of QA samples withdrawn during compression, 0.200 kg.

Done By: <u>AV</u>	Date: <u>11/20/07</u>	Checked By: <u>pmt</u>	Date: <u>11/20/07</u>
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5. Usable Final Blend Weight in Step # 31, Page # 16, 503.25 kg.

Done By: <u>K.V.P.</u>	Date: <u>11/21/07</u>	Checked By: <u>K.D.</u>	Date: <u>11/21/07</u>
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6. Calculation of tablet compression yield:

Quantity of Tablets Produced (Step # 3)

$$\frac{\text{Quantity of Tablets Produced (Step \# 3)}}{\text{Final Blend Weight (Step \# 5)}} \times 100 = \% \text{ Yield}$$

$$\frac{499.24 \text{ kg}}{503.25 \text{ kg}} \times 100 = 99.20 \% \text{ Yield}$$

NOTE: The Yield should be within 95.0 - 101.0%. If the Yield is outside of 95.0 - 101.0%, notify the Department Supervisor and determine the cause of the variance.

REMARKS:

Done By: <u>K.D.</u>	Date: <u>11/21/07</u>	Checked By: <u>pmt</u>	Date: <u>11/21/07</u>
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COPY

## Actavis Totowa LLC

Page 23 of 24 <sup>52</sup> 6/25/08

MPR #: 14504	Rev #: 08	Effective Date: 6/16/06	Batch #:
Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)			70924A
Batch Size: 4,800,000 Tablets			

COMPRESSION

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7. Production Management review and approval of the batch record.

Done By: K.D.	Date: 11/21/07
Done By: EVR	Date: 11/21/07

8. Quality Assurance compressed tablets approval and review of the batch record.

QA Approval By: SSM	Date: 11/28/07
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ACTAVIS TOTOWA LLC

## EQUIPMENT USAGE AND CLEANING LOG

EQUIPMENT DESCRIPTION: STAKES TABLET PRESSEQUIPMENT ID NUMBER: 67BB2-45st

PRODUCT NAME (#)	BATCH NUMBER	DATE & TIME BATCH STARTED	DATE & TIME BATCH COMPLETED	TYPE OF CLEAN (WET/DRY) DOI/REV #	DATE/TIME CLEANING STARTED	DATE/TIME CLEANING COMPLETED	CLEANED BY DATE	CHECKED BY DATE
<del>Digoxin Tabs, USP 0.25mg (146)</del>	<del>70813A</del>	<del>2:55 PM</del>	<del>10:45 AM</del>	<del>022-06</del>	<del>11:00 AM</del>	<del>2:05 PM</del>	<del>SPB</del>	<del>pmg</del>
<del>Digoxin Tablets USP 0.25mg (146)</del>	<del>70832A</del>	<del>2:28 PM</del>	<del>11:30 AM</del>	<del>022-06</del>	<del>10:28/07</del>	<del>10:28/07</del>	<del>10/28/07</del>	<del>10/28/07</del>
<del>Digoxin Tablets USP 0.25mg (146)</del>	<del>70832A</del>	<del>2:28 PM</del>	<del>11:30 AM</del>	<del>022-06</del>	<del>10:28/07</del>	<del>10:28/07</del>	<del>10/28/07</del>	<del>10/28/07</del>
<del>Digoxin Tablets USP 0.25mg (146)</del>	<del>70833A</del>	<del>3:20 PM</del>	<del>10:00 AM</del>	<del>022-06</del>	<del>10:15 AM</del>	<del>2:30 PM</del>	<del>SMP</del>	<del>pmg</del>
<del>Digoxin Tablets USP 0.25mg (146)</del>	<del>70834A</del>	<del>11:05 AM</del>	<del>9:50 AM</del>	<del>022-06</del>	<del>10:05 AM</del>	<del>12:30 PM</del>	<del>SMP</del>	<del>pmg</del>
<del>Digoxin Tablets USP 0.25mg (146)</del>	<del>70835A</del>	<del>2:25 PM</del>	<del>12:30 PM</del>	<del>022-06</del>	<del>12:40 PM</del>	<del>3:15 PM</del>	<del>SPB</del>	<del>NMP</del>
<del>Digoxin Tablets USP 0.25mg (146)</del>	<del>70836A</del>	<del>3:30 PM</del>	<del>4:50 PM</del>	<del>022-06</del>	<del>4:50 PM</del>	<del>1:00 PM</del>	<del>CS</del>	<del>NMP</del>
<del>Digoxin Tablets USP 0.125mg (145)</del>	<del>70924A</del>	<del>11:17/07</del>	<del>2:10 PM</del>	<del>022-06</del>	<del>2:15 PM</del>	<del>3:10 PM</del>	<del>AV</del>	<del>pmg</del>
<del>Digoxin Tablets USP 0.125mg (145)</del>	<del>70925A</del>	<del>3:15 PM</del>	<del>8:00 AM</del>	<del>022-06</del>	<del>8:05 AM</del>	<del>6:45 PM</del>	<del>GAH</del>	<del>CS</del>

Attachment #6 Sub 01/25/08 Sub 01/25/08 54 p. 52 of 67  
 Sub 01/25/08

Actavis  
 Totowa LLC

Quality Assurance

**Digoxin Tablets 0.125mg  
 Lot 70924A1 100% Inspection Protocol  
 (Investigation 07-093)**

**Overview:**

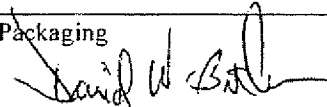
During the packaging and filling operation of batch 70924A1, two tablets of Digoxin 0.125 mg were observed with approximately double the thickness. Packaging operators inspected the tablets in the hopper as well as two subsequent product buckets for thicker tablets and found a total of five thicker tablets during the inspection. Quality Assurance subsequently put the batch on HOLD (H07-089) and investigation 07-093 was initiated.

According to this protocol, a 100% inspection on all tablets of the subject batch will be conducted at the Taft Road facility. Since the tablets have already been packaged, the bottles will need to be emptied and the bulk tablets 100% inspected.

A total of 4722 bottles of 1000 count tablets have been packaged which equates to approximately 4,722,000 tablets. Container ID labels for the bulk product and line ID labels will be issued by Documentation.

This inspection is being performed to ensure that all defect tablets have been removed from the batch. The type of defect to be inspected for will be reviewed with the inspectors. All tablets that are found to be double the thickness will be reported and rejected. Upon completion of this protocol, an AQL sample protocol will be written for Quality Assurance to evaluate the effectiveness of the 100% inspection.

Approved By:

Packaging \_\_\_\_\_ Date: \_\_\_\_\_  
  
 Quality Assurance \_\_\_\_\_ Date: 01/11/08

Actavis  
Totowa LLC

Quality Assurance

**Digoxin Tablets 0.125mg**  
**Lot 70924A1 100% Inspection Protocol**  
**(Investigation 07-093)**

**Overview:**

During the packaging and filling operation of batch 70924A1, two tablets of Digoxin 0.125 mg were observed with approximately double the thickness. Packaging operators inspected the tablets in the hopper as well as two subsequent product buckets for thicker tablets and found a total of five thicker tablets during the inspection. Quality Assurance subsequently put the batch on HOLD (H07-089) and investigation 07-093 was initiated.

According to this protocol, a 100% inspection on all tablets of the subject batch will be conducted at the Taft Road facility. Since the tablets have already been packaged, the bottles will need to be emptied and the bulk tablets 100% inspected. A total of 4722 bottles of 1000 count tablets have been packaged which equates to approximately 4,722,000 tablets. Container ID labels for the bulk product and line ID labels will be issued by Documentation.

This inspection is being performed to ensure that all defect tablets have been removed from the batch. The type of defect to be inspected for will be reviewed with the inspectors. All tablets that are found to be double the thickness will be reported and rejected. Upon completion of this protocol, an AQL sample protocol will be written for Quality Assurance to evaluate the effectiveness of the 100% inspection.

Approved By:

*A. Heshidan*

Date:

02/11/08

Packaging

Date:

Quality Assurance

P. 01

Jan 11 2008 16:59

FAX: 19738907880

ACTAVIS TOTOWA LLC

**Digoxin Tablets 0.125mg**  
**Lot 70924A1 100% Inspection Protocol**  
**(Investigation 07-093)**

Total Bulk Inspected:

- 33 Full Drums X 15.00 KG = 495.00 KG
- 1 Partial Drum X 3.48 KG = 3.48 KG
- Total 498.48 KG

Use form # F-PRD-219-A-00 for documenting "Inspected By"

Inspection Results Reviewed By:

<u>AR</u> QA Packaging	Date: <u>01/18/08</u>
<u>David W. B...</u> Quality Assurance Director	Date: <u>01/19/08</u>

P.02

Jan 11 2008 16:59

Fax: 19738907980

ACTAVIS TOWNA LLC

F-PRD-219.A.00

8/5/19  
6/5/18  
6/5/17  
6/5/16  
6/5/15

80/51/10

PLAINTIFFS'

ACTAVIS TOTOWA LLC

PRODUCT NAME (#): Digoxin Tablets 0.125mg (145)  
BATCH #: 70924H1  
THR 01/15/08  
PACKAGING AREA #: 1108

PACKAGING AREA #: 1108

BATCH #: 70924A1

8015110 YHC

control



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Actavis, Totowa LLC

Digoxin Tablets 0.125 mg (Lot # 70924A1)  
BULK WEIGHT DOCUMENTATIONJab  
01/25/0858  
P. 56 of 67  
Jab  
01/25/08

BUCKET #	GROSS WT	TARE WT	NET WT
1	16.00	1.00	15.00
2	16.00	1.00	15.00
3	16.00	1.00	15.00
4	16.00	1.00	15.00
5	16.00	1.00	15.00
6	16.00	1.00	15.00
7	16.00	1.00	15.00
8	16.00	1.00	15.00
9	16.00	1.00	15.00
10	16.00	1.00	15.00
11	16.08	1.08	15.00
12	16.08	1.08	15.00
13	16.08	1.08	15.00
14	16.08	1.08	15.00
15	16.08	1.08	15.00
16	16.00	1.00	15.00
17	16.00	1.00	15.00
18	16.00	1.00	15.00
19	16.00	1.00	15.00
20	16.00	1.00	15.00
21	16.08	1.08	15.00
22	16.00	1.00	15.00
23	16.00	1.00	15.00
24	16.08	1.08	15.00
25	16.00	1.00	15.00
26	16.00	1.00	15.00
27	16.00	1.00	15.00
28	16.08	1.08	15.00
29	16.08	1.08	15.00
30	16.08	1.08	15.00
31	16.00	1.00	15.00
32	16.08	1.08	15.00
33	16.08	1.08	15.00
34	4.56	1.08	3.48
35			

ACTAVIS TOTWA LLC

PAGE # 1 OF 1

On Line Product Inspection Form

Product Name(#): Digoxin Tablets 0.125mg (145) Batch #: 70924A1

Area # 408

Observation:

Observed By: \_\_\_\_\_ Date: \_\_\_\_\_ Production Management: \_\_\_\_\_ Date: \_\_\_\_\_

Action to be taken:

*N/A. See attached protocol*  
*DMS*  
*01-15-08*

Production Management: \_\_\_\_\_ Date: \_\_\_\_\_ QA Approval: \_\_\_\_\_ Date: \_\_\_\_\_

1. Check for cleanliness Production Room/Area and Utensils as per requirement.

Room/ Area # 408

Done By: JHR Date: 01/15/08 Checked By: M.D.S. Date: 01/15/08

QA Approval By: SPK Date: 01/15/08

2. Inspect the Tablets/Capsules on the stainless steel trays covered with parchment paper.

Done By: PYD Date: 01/15/08 Checked By: JHR Date: 01/15/08

Weight of Rejects: 0.08 Kg

Management Comment: Total of 15 Tablets with Approx. double the thickness were removed during inspection of this batch. The removed tablets are attached with this protocol.

Production Management: DMS Date: 01-18-08

QA Approval: DeFu Date: 01/18/08

1/15/2008

F-PRD-219.B.00

Actavis  
Totowa LLC

Quality Assurance

**Digoxin Tablets 0.125mg**  
**Lot 70924A1 Tightened AQL Inspection**  
**(Investigation 07-093)**

**I. Overview:**

During the packaging and filling operation of batch 70924A1, two tablets of Digoxin 0.125 mg were observed with approximately double the thickness. Packaging operators inspected the tablets in the hopper as well as two subsequent product buckets for thicker tablets and found a total of five thicker tablets during the inspection. Quality Assurance subsequently put the batch on HOLD (H07-089).

According to a QA provided inspection protocol, batch 70924A1 was 100% inspected by the packaging department for thicker tablets. The inspection criterion were reviewed with the inspectors prior to the inspection to ensure the acceptability of the product for release to the market. The inspection was completed and a total of 15 tablets with approximately double the thickness were removed from the entire batch. This is in addition to five tablets removed during the packaging operation.

The QA team will conduct a high level tightened AQL inspection to ensure the defect tablets have been removed from the batch.

**II. AQL Sample Plan:**

Digoxin Tablets 0.125mg have a theoretical batch size of 4,800,000 tablets.

The AQL sample will be pulled by QA based on the following:

- AQL level = 0.065
- Sample plan = single, tightened level I
- Sample Size Code = Q
- Bulk size = Approximately 4,747,428 (4,800,000 Theoretical)
- Inspect 1250 tablets (minimum)
  - 40 tablets will be inspected from the 33 full drums (1320 tablets)
  - 10 tablets will be inspected from the 34<sup>th</sup> drum (1/5 full)
  - Tablets will be taken randomly from each drum
- Accept on 1 / Reject on 2 (total for batch)

Approved By:

Packaging

Date:

Quality Assurance

Date:

COPY

Digoxin Tablets 0.125mg  
 Lot 70924A1 Tightened AQL Inspection  
 (Investigation 07-093)

6/1/08  
6/1/086/1/08  
6/1/08

DRUM NUMBER	NUMBER OF TABLETS INSPECTED	NUMBER OF TABLET DEFECTS	TYPE OF DEFECT	INSPECTED BY DATE
1	40	0	None	AR 01/22/08
2	40	0	None	AR 01/22/08
3	40	0	None	AR 01/22/08
4	40	0	None	AR 01/22/08
5	40	0	None	AR 01/22/08
6	40	0	None	AR 01/22/08
7	40	0	None	AR 01/22/08
8	40	0	None	AR 01/22/08
9	40	0	None	AR 01/22/08
10	40	0	None	AR 01/22/08
11	40	0	None	AR 01/22/08
12	40	0	None	AR 01/22/08
13	40	0	None	AR 01/22/08
14	40	0	None	AR 01/22/08
15	40	0	None	AR 01/22/08
16	40	0	None	AR 01/22/08

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Digoxin Tablets 0.125mg  
 Lot 70924A1 Tightened AQL Inspection  
 (Investigation 07-093)

b6  
b7C  
01/25/08b2  
p. 61 of 67  
01/25/08

DRUM NUMBER	NUMBER OF TABLETS INSPECTED	NUMBER OF TABLET DEFECTS	TYPE OF DEFECT	INSPECTED BY / DATE
17	40	0	NONE	AR 01/22/08
18	40	0	NONE	AR 01/22/08
19	40	0	NONE	PBP 01/22/08
20	40	0	NONE	PBP 01/22/08
21	40	0	NONE	AR 01/22/08
22	40	0	NONE	AR 01/22/08
23	40	0	NONE	AR 01/22/08
24	40	0	NONE	PBP 01/22/08
25	40	0	NONE	AR 01/22/08
26	40	0	NONE	AR 01/22/08
27	40	0	NONE	PBP 01/22/08
28	40	0	NONE	AR 01/22/08
29	40	0	NONE	AR 01/22/08
30	40	0	NONE	PBP 01/22/08
31	40	0	NONE	PBP 01/22/08
32	40	0	NONE	AR 01/22/08
33	40	0	NONE	AR 01/22/08
34	10	0	NONE	AR 01/22/08

Inspection Results Reviewed By:

P. Baughoff

Date:

01/22/08

QA Packaging

David W. Bahl

Date:

01/22/08

Quality Assurance Director

Attachment # 8

Ans  
01/25/08

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Ans  
01/25/08

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Ans  
01/25/08

is Totowa LLC

EQUIPMENT ID LABEL

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Prod ID: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Equipment Id: # 583

Equipment Name: Safe Line Metal Detector

Batch #: 70924A Manufacturing Start Date: 11/17/07

Manufacturing Stage/Dept: Compression

<14504-08>



Actavis Totowa LLC

METAL DETECTOR DATA SHEET

**COPY**

Page 1 of 1

Prod Id: 145 Prod Name: Digoxin Tablets, USP 0.125 mg Batch #: 70924A Date: 11/17/07  
 Equipment I.D.: 583 ~~70924A~~

- Step 1. Supervisor will set-up the Metal Detector and test. Supervisor signature verifies that sensitivity/threshold reading is correct. Record results in the proper column.  
 Step 2. Operator confirms and records results in the proper column.  
 Step 3. Operator will repeat the test at the beginning of each day and at the end of the run.

DATE	TIME (AM/PM) *	SUPERVISOR'S SIGNATURE	OPERATOR'S SIGNATURE	PASS	FAIL
11/17/07	3:40 AM/PM	pmc		✓	
11/17/07	3:42 AM/PM		SPC	✓	
11/18/07	7:05 AM/PM		AV	✓	
11/19/07	7:35 AM/PM		AV	✓	
11/20/07	7:35 AM/PM		AV	✓	
11/20/07	1:35 PM AM/PM		AV	✓	
	AM/PM				
	AM/PM				
	AM/PM				
	AM/PM				
	AM/PM				
	AM/PM				
	AM/PM				
	AM/PM				

\* Circle AM/PM

SUPERVISOR REVIEW: K.D.

DATE: 11/21/07

AV  
11/18/07

**COPY**

AV  
11/20/07

AV  
11/21/07  
6/15/08

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Totowa LLC

EQUIPMENT ID LABEL

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Prod ID: 145

Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Equipment Id: # 582

Equipment Name: Sqfeline Metal Detul Detector

Batch #: 70924A

Manufacturing Start Date: 11/17/07

Manufacturing Stage/Dept: Compression

<14504-08>

PLAINTIFFS' EXHIBITS 000066

ACTAV 000002620

Actavis Totowa LLC

## METAL DETECTOR DATA SHEET

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Page 1 of 1

Prod Id: 145 Prod Name: Digoxin Tablets, USP 0.125 mg Batch #: 70924A Date: 11/17/07  
 Equipment I.D.: 582

- Step 1. Supervisor will set-up the Metal Detector and test. Supervisor signature verifies that sensitivity/threshold reading is correct. Record results in the proper column.  
 Step 2. Operator confirms and records results in the proper column.  
 Step 3. Operator will repeat the test at the beginning of each day and at the end of the run.

DATE	TIME (AM/PM) *	SUPERVISOR'S SIGNATURE	OPERATOR'S SIGNATURE	PASS	FAIL
11/17/07	3:10 AM/PM	pmc		✓	
11/17/07	3:17 AM/PM		SPC	✓	
11/18/07	7:20 AM/PM		AV	✓ AV 11/18/07	✓
11/18/07	7:28 AM/PM		AV	✓	
11/19/07	7:46 AM/PM		AV	✓	
11/20/07	7:48 AM/PM		AV	✓	
11/20/07	11:30 AM/PM		AV	✓	
	AM/PM				
	AM/PM				
	AM/PM		AV 11/20/07		
	AM/PM				
	AM/PM				
	AM/PM				
	AM/PM				

\* Circle AM/PM

SUPERVISOR REVIEW: kdDATE: 11/21/07

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11/18/07

11/18/07

Attachment #1  
Jus 01/25/08

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Jus 01/25/08

## TRAINING COMPLETION RECORD

SOP/Course Title: <u>Preventative Action training for Digoxin Tablets USP, 125g Investigation # 07-093</u>			
Length of Time: <u>20</u> Hours <u>Minutes</u>		Training Date: <u>01/24/08</u>	
SOP/DOI No.: <u>Investigation # 07-093</u>		Revision No.: <u>N/A</u> <u>01/24/08</u>	
Check all that apply: <input checked="" type="checkbox"/> On-The-Job-Training <input type="checkbox"/> Classroom Training <input type="checkbox"/> Revision/Refresher Training			

By signing this document, I am confirming that I have received the above training topic and that I understand how it relates to my job duties.

Training ID #	Print Name	Signature	Department
2000172	MAHENDRA S. PATEL	Mahendra S. Patel	Compression
2000151	Manubhai I. Patel	Manubhai I. Patel	Compression
2000138	Gordhambhai S. Patel	Gordhambhai S. Patel	Compression
2000311	Suryakant M. Patel	SM Patel	Compression
2000180	Prakash Patel	Prakash Patel	Compression
2000148	Chandrasekar R. Patel	CR Patel	Compression
2000241	N. S. Leshkumar N. Patel	N. S. Leshkumar	Compression
2000617	Alexis Velez	Alexis Velez	Compression
2000223	Suresh B. Patel	Suresh Patel	Compression
2000603	CARLOS SOTO	Carlos Soto	Compression
2000189	Kirit Patel	Kirit Patel	Compression
2000218	Akshat Mishra	Akshat Mishra	Encapsulation
2000231	BHARAT K. PATEL	BK Patel	Compression
2000158	Suresh R. Patil	Suresh R. Patil	Compression
N/A			

01/24/08

Comments:

DN/A

TRAINER		
Print Name:	<u>Eric V. Sandoz</u>	Dept #: <u>Compression</u>
Signature:	<u>[Signature]</u>	Date: <u>01/24/08</u>

TRAINING DOCUMENTATION GROUP USE ONLY

Computer Entry By: \_\_\_\_\_ (Signature/Date)  
Session ID: \_\_\_\_\_